Reviewer’s report

Title: Obstacles to researching the researchers: A case study of the ethical challenges of undertaking methodological research investigating the reporting of randomised controlled trials

Version: 1 Date: 24 July 2009

Reviewer: Davina Ghersi

Reviewer’s report:

Thank you for asking me to review this manuscript of a case study that is being used to demonstrate some of the problems associated with trying to perform methodological research using the records kept by research ethics committees. By discussing their experience the authors have comprehensively considered and described many of the legal and ethical challenges. I found it both pertinent and interesting. This is an important topic and I have a few suggestions that the authors can take or leave.

At the heart of this manuscript is the fact that the investigators "did not plan to obtain consent from trialists to access their ethics application". What is not addressed in the manuscript is why "consent" in the ethical sense is even relevant in this instance given that the proposed research was on the documentation submitted as part of an application for ethics approval and not research on human beings. The subject of the research is the clinical trial and not the investigator. For the aspects of the research that asks investigators to complete a survey I can understand that some form of consent would be required as the trial investigators are the human beings being researched. However, how do you obtain consent from a clinical trial protocol for it to be used as the subject of research? What are the "benefits risks and burdens" to the trial documentation if it is used in research? This doesn't seem logical.

It would seem that this should be an administrative and not an ethical decision and hence it could be argued that permission to access the records should be asked of the hospital administration to which the ethics committee report rather than from the ethics committee themselves who are potentially conflicted. This in turn raises the issue of who actually owns the records kept by research ethics committees. This also is not addressed (and I appreciate that it may be difficult to ascertain).

The manuscript does not currently refer to the issue of accountability and transparency of RECs and would perhaps benefit by doing so. As a suggestion the authors may want to refer to the debate sparked by Ashcroft and Pfeffer (http://www.bmj.com/cgi/content/full/322/7297/1294) when they argued that the secrecy behind RECs and their decision making is unjustified. Schuklenk and Lott also discussed transparency specifically in relation to ethics committees. http://www.udo-schuklenk.org/files/bppa.pdf
"Transparency is critical for public policy committees to maintain and establish integrity and produce reputable results. … Unfortunately most public bioethics committees do choose to meet behind closed doors and forgo transparency, creating suspicion among other professional bioethicists and the rest of the public, even when in fact there may be no justifiable grounds for believing something to be amiss. … Bioethical advice administered without transparency ushers in uncertainty."

A workshop on this topic was run by the UK’s National Research Ethics Service (NRES) in 2007. http://www.bmj.com/cgi/content/full/322/7297/1294 Among other things, participants in the workshop concluded that legally "RECs have a duty to provide information and details and compliance need to be encouraged and facilitated", and also acknowledged the relationship between openness, audit and quality assurance.

**Level of interest:** An article of outstanding merit and interest in its field

**Quality of written English:** Acceptable

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**

I declare that I have no competing interests