Reviewer’s report

Title: Procedure vs process: ethical paradigms and the conduct of qualitative research

Version: 1 Date: 20 June 2012

Reviewer: Edwin van Teijlingen

Reviewer’s report:

Procedure vs process: ethical paradigms and the conduct of qualitative research
Kristian Pollock

Interesting overview highlighting the recent two decades of changes in research ethics procedures in the UK and the unintended consequences for qualitative research (but also for epidemiological research) of an individualistic focus based on a biomedical approach. This is not the first paper of its kind, indeed the author quotes many relevant (similar) papers herself. However, it is an interesting and important debate paper on the pressure on qualitative research due to this developments driven by ethical considerations and procedures established to deal with biomedical quantitative research. The debate addresses an important problem of interest to a broad medical audience, not just to a more limited group of qualitative researchers and/or users of qualitative research.

Major compulsory revisions

Abstract should refer to the UK, as the bureaucratization of ethics is very a British problem as portrayed in this paper, although from reading comments from across the globe is it not solely a British problem. This paper is largely focused on the UK, hence should be made clear in the beginning to the reader.

Page 4 offering 23 references seems over the top, e.g. [3-26]. I would have though three or four key references to make the general point is more than enough. Overall 150 references for a single paper in BMC Medical Ethics is way too much. Drop the irrelevant ones and keep as much as possible the open access papers to give easy access for interested reads across the globe.

The ‘Summary / Conclusion’ section is neither a Summary nor a Conclusion. It is much more a continuation and repeat of the Discussion with far too many references included. I would not expect any more references in a Conclusion/Summary. This needs to be rewritten as true summary.

Minor compulsory revisions

Should title be ‘versus’ not ‘vs’? Try: ‘Procedure versus process: ethical paradigms and the conduct of qualitative research’

In the text give abbreviations in full on first use, consider the international readership of BMC Medical Ethics. Hence give UK, NHS, US FDA, AMS, NRES, BSA, ASA, etc in full on first use. REC is used on page 5 but not explained in full
until later page.

On page 4 give a few references as examples for the statement ‘and other
developed nations .. ’.

Page 5 the sentence “This paper considers the implications of current legal
constraints alongside contrasting ethical paradigms for the conduct of qualitative
research, particularly in sensitive and difficult areas such as palliative and end of
life care, for which such methods of investigation are particularly suitable and the
need for further research is pressing.”

This sentence should perhaps read: “This paper considers the implications of
current UK legal constraints alongside contrasting ethical paradigms for the
conduct of qualitative research, particularly in sensitive and difficult areas such
as palliative and end of life care, for which such methods of investigation are
particularly suitable and the need for further research is pressing.

Page 6 the word ‘Western’ seems superfluous in the sentence: “Similar
processes and regulatory structures have developed in other Western nations in
Europe, the US, Canada and Australia [54].”

Page 12 “including the Universities” does not need a capital “including the
universities…”

Page 12 explain what “The bioethical valorisation…” means!

Page 13 I am not sure what PIS stand for in “provided in the PIS may…. ”

References:
Ref. 25
seems to have text missing : Rumbold B, Lewis G, Bardsley M: Access to
person-level data in health care In: xxxxxxxxxxxxxxxxxxxxxxxxxxxx.: Nuffield Trust;
2011.

Ref. 29 and 36
Too many capitals in JOURNAL TITLE in, for example
van Teijlingen E, Douglas F, Torrance N: Clinical governance and research
ethics as barriers to UK low-risk population-based health research? . BMC
PUBLIC HEALTH 2008, 8(396).

Ref 55
No need for capital ‘5th ’ in 5TH edn.

Too many references have an ‘In.:’ which is not needed or incomplete (it seems).

**Level of interest:** An article whose findings are important to those with closely
related research interests

**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'