Reviewer’s report

Title: The development of a standard training toolkit for research studies which recruit pregnant women in labour.

Version: 1 Date: 25 September 2013

Reviewer: Ed Juszczak

Reviewer’s report:

Discretionary Revisions –

Abstract:

2nd sentence “Regulation is unclear…” – perhaps this statement is too ambiguous; regulation typically is clear, it is the interpretation that often lacks clarity or consistency. I suggest that this generalisation could be replaced by something that hits straight to the heart of the issue. Perhaps the authors are trying to say something like “The requirements of GCP in the clinical trials environment are not consistently, nor always appropriately, applied …”

In addition, it may be wise to stress that the implications of such ‘uncertainty’ often result in unnecessary barriers to participation (both of clinicians and therefore participants; a lose-lose situation).

Background:

1st paragraph – perhaps a better word than ‘tension’ would be ‘uncertainty’?

2nd paragraph – I think the reader would benefit from greater clarity in the description of the HOLDS protocol (assuming no context or content knowledge), and clarification of exactly who decided whether clinicians were permitted to recruit women in labour.

3rd paragraph – the sentence starting “Others stipulated…” – perhaps the authors could clarify exactly who these others were in terms of their role at the hospital, and confirm that these others were suggesting that GCP trained staff were by definition research-experienced, because surely one does not always imply the other.

4th paragraph – please correct brackets around (UK)

Contents of the toolkit:

2nd paragraph – towards the end it is suggested that ‘training materials are developed by the sponsor’; I would have thought agreed/approved, but not developed by the sponsor.

5th paragraph – re ‘documentation of the consent process’; I suggest stressing the importance of the correct documentation of the consent process.
Level of interest: An article of importance 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'