Author's response to reviews

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

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Author's response to reviews: see over
Dear Sir

Thank you for your consideration of the letter we submitted. Here are the point by point responses to the reviewer’s comments:

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).

  Thank you – we have altered the manuscript.

Background

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

  Thank you – we have changed this.

- 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.

  Thank you – we are reluctant to add too much detail regarding the HOLDS pilot but have added that the women were in delayed labour and a reference for the published pilot.

- 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.

  Thank you – we have added this information.

- 4th paragraph – please correct brackets around (UK)

  Thank you – we have corrected this.

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.

  Thank you – we have amended this.

- 5th paragraph – re ‘documentation of the consent process’; I suggest stressing the importance of the correct documentation of the consent process.

  Thank you – we have added this.

We do hope that we have addressed the issues raised and that you will agree to publish this letter. Thank you for your consideration.

Yours sincerely

Sara Kenyon