Reviewers report

Title: Issues of informed consent for intrapartum trials: A proposed consent pathway from the experience of the RELEASE trial (ISRCTN13204258)

Version: 1 Date: 28 November 2005

Reviewer: Alan R Tait

Reviewers report:

General
This is a well-written article describing some of the ethical and practical issues related to obtaining informed consent for research involving parturients. A proposed pathway for obtaining consent based on the Release trial is presented.

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Major Compulsory Revisions (that the author must respond to before a decision on publication can be reached)

The authors need to clearly distinguish between consent for treatment (e.g., an epidural) versus consent for research. While the principles are similar, the requirements for information may be quite different. This is particularly true when describing the risks and benefits of treatment versus those of research. Whereas it may be perfectly acceptable to provide selected information regarding treatment per the patient’s preferences, it may be ethically and legally indefensible to withhold study-specific information.

There is no discussion regarding the importance of enhancing and verifying the subjects’ understanding of study information. This is particularly important given that consent for parturients may be sought at a time when the subject is most vulnerable. Although the authors cite an article stating that understanding of epidural risks was independent of the patient’s parity or pain level, several studies have shown that even under non-stressful circumstances, many research subjects have limited understanding of the elements of consent. Thus, it begs the question as to how well information can be assimilated under the stress of labour. A discussion of how the presentation of research information can be optimized to enhance understanding and how this understanding might be verified should be included.

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Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)

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Discretionary Revisions (which the author can choose to ignore)

The use of website/flyers for presenting research information is a potentially useful approach to educate prospective subjects prior to obtaining consent. However, there are limitations to this approach that should be discussed. For example, not all subjects have access to computers, and for small sized studies, the use of these media may be prohibitively expensive.

Research involving children, the elderly, and the cognitively impaired often require consent using a surrogate or proxy decision-maker. The authors may want to comment on the potential use of surrogates for situations involving consent sought during labor.
Many consider that consent sought for research by the subject’s health care provider i.e., anesthetist, obstetrician, to be potentially coercive. The authors might want to discuss the importance of consent sought by an independent party, particularly given the vulnerability of this research population.

**What next?:** Unable to decide on acceptance or rejection until the authors have responded to the major compulsory revisions

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

**Quality of written English:** Acceptable

**Declaration of competing interests:**

I declare that I have no competing interests