Reviewer's report

Title: Impact of Gender-based Social Dynamics on the Decision to Voluntarily Participate in a Clinical Trial

Version: 4  Date: 25 March 2014

Reviewer: Susan Bull

Reviewer's report:

This is a very interesting paper addressing an important issue in research. Below are some recommendations for areas to consider further.

Discretionary Revisions (which are recommendations for improvement but which the author can choose to ignore)

1. I think this paper would be strengthened by more information about the questionnaire including the text of the questions and what kinds of responses could be given by participants, whether there were any forced choice answers etc.

2. The limitations of the work are not examined. One that it might be useful to consider are whether the delay of one month between consent and the questionnaire was considered likely to affect responses (a gap of that amount when understanding of research is being assessed turns the study into a test of recall rather than understanding, the researchers may feel that it is of less relevance in this study which is assessing decision-making and awareness of researchers rights).

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

3. Introduction:
   a. Paragraph 3 in the introduction sets out well the concept of gender and potential effects of socially constructed gender roles, but may benefit from doing so more critically. To what extent so such roles really determine what to think, how to act, and relationships – and to what extent can women engage with and negotiate the effects of such roles? Research from African setting suggests that there are a number of ways in which decisions are reached about research and that in some contexts women reach decisions on behalf of themselves and their children without consultation.
   b. In paragraph 5 of the introduction, the final sentence suggests strategies to ensure the autonomy of research participants. This is a very large claim and there are concerns about whether or not stronger forms of autonomous decision-making should be required of participants. Would it be better to limit this to the factors of consent outlined earlier, that it be informed, voluntary etc.

4. Methodology –
   a. paragraph 1 - reasons for non-participation are set out for 26 non-participants,
what about the other 5 – if no reason given it would be good to say so.

b. Paragraph 2 - It would be useful to know more about the other questionnaires – I’m not sure what it means to say they are used by a Resolution of the National Health Council, a resolution can’t use questionnaires.

5. Discussion

a. To assume that influences of husband and family are uniformly more present in developing countries, rather than ‘developed’ ones, based on one cited study could be considered over-generalising given the heterogeneity of the context - is such a broad claim necessary?

b. The paragraph beginning ‘The image transfer’ I found difficult to understand, particularly the final sentence. Is it important to the argument that the researcher is seen as a doctor to be considered influential in decision-making? Would the sex of the researcher recruiting participants into the clinical trial (which is not discussed in this paper) be more relevant to this study than whether or not they were perceived as being a doctor than a researcher?

c. When discussing participants’ awareness of alternatives to participation in the second to last paragraph of this section, you’ve noted two paragraphs earlier, that in some contexts where participants have considered that clinical research is the only means of obtaining a certain treatment, they are absolutely correct, such as in the context of receiving antiretrovirals for HIV in African settings. Thus differences in views about alternatives may simply be accurate reflections of realities of what is and is not available in specific resource poor settings for particular conditions. Are you arguing that those being recruited into trials should have a right to have an alternative treatment available? This may make it problematic to conduct some studies.

6. Final considerations

a. Your first paragraph suggests that all women in research, even if considered autonomous, should be labelled as extrinsically vulnerable. There are a few concerns about this statement: First, as currently written that is a very broad category to label as vulnerable (all women in the world). There have already been concerns that instruments such as versions of the Declaration of Helsinki have inappropriately broadened categories of vulnerability such that the majority of, if not all, research participants can be considered vulnerable.

b. Labelling a population as vulnerable has multiple effects, it requires that additional consideration is given to measures to support free decision-making, as you discuss. However, it may also limit the kinds of research that can be conducted with a population. Many guidelines for example will limit the risk levels that can be present in research with vulnerable populations. Are you wishing to limit the kinds of research that women can participate in?

c. Your second and third to last paragraph make good points and could be expanded. Your final paragraph in this section doesn’t seem to follow from the material in the rest of the section, perhaps it would be stronger at the beginning of the discussion section or in the introduction of the paper.

7. References
Many of the references are incorrectly numbered in the text, eg. the ref to 32 in the text should be to 33, the ref to 33 should be to 34 etc.

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

8. One potential limitation of this paper that should be discussed is that some research demonstrates that reporting of voluntariness in research may not be straightforward, with people being unwilling to report that their decisions are influenced. If there is a gender difference in unwillingness to report influences on decision-making (i.e. men like to be seen as making their own decision and are less likely to report influences) then this may account for some of the findings reported in this paper. See the following for example.


Susan Bull & Graham Charles Lindegger (2011): Ensuring Consent to Research is Voluntary: How Far Do We Need to Go?, The American Journal of Bioethics, 11:8, 27-29

9. It is important to reflect on whether the reported influences on decision-making are problematic for women. The fact that consultation has taken place, and a decision has been influenced, may not mean that the decision was less voluntary. There are studies that recognise that some participants prefer to make decisions following consultation with respected others, and that such influences are considered to strengthen, rather than diminish, their free decision-making. Studies from African settings also report that women may seek to consult with husband and report that they have declined approval of the research as a socially acceptable way of declining to take part, rather than declining to take part directly, which can be perceived as rude (see research from CSS Molyneux, D Kamuya and V Marsh in Kenya for example).

Level of interest: An article of importance in its field

Quality of written English: Needs some language corrections before being published

Statistical review: Yes, but I do not feel adequately qualified to assess the statistics.

Declaration of competing interests:

I declare that I have no competing interests.