Reviewer's report

Title: Eligibility determination for clinical trials: development of a case review process

Version: 1 Date: 7 July 2014

Reviewer: Fiona Simpson

Reviewer's report:

Thank-you for asking me to review this interesting manuscript.

- Minor Essential Revisions

1. I note the additional files and table 1 providing details on the inclusion and exclusion criteria of the three trials. Is this the exact wording of the inclusion and exclusion criteria from the three trials, or a summary the authors used for case presentation? Please clarify in your manuscript.

2. On page 7, please provide more details in your manuscript as to who serves as the ‘moderator’?

3. Please provide more details as to how the ‘poll’ is conducted during the meetings. Is it anonymous for example?

4. On page 9, the authors discuss that 72 participants were deemed eligible but decided not to participate or were later excluded. Do the authors have a breakdown of the numbers in each category? If so, please add to the manuscript.

5. In table 2, do you have figures to add to the table that would provide more details as to why participants who were eligible did not ultimately enroll in the trial? If so, please add to your manuscript.

6. Page 10 sentence beginning “Three of the 96 eligible”... The authors have listed three reasons for exclusion. Could you please clarify in your manuscript the number of patients that used each of the reasons given? You have previously stated that potential subjects could be excluded for multiple reasons.

7. In your limitations section of your discussion, please discuss in more detail that there is room for exclusion and hence selection bias at the initial step where the study volunteers are screened at the baseline visit by (one) study coordinator.

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 have no competing interests