Reviewer's report

Title: Confronting diversity in the production of clinical evidence goes beyond the mere inclusion of underrepresented groups in clinical trials

Version: 1 Date: 25 January 2013

Reviewer: Stacie Geller

Reviewer's report:

This paper provides an argument for a wider view of diversity issues in clinical research. The authors contend that rather than seeing diversity as a departure from the normative assumption of homogeneity in clinical trials, researchers should approach the production of clinical knowledge with an assumption of heterogeneity instead. This approach would permeate all aspects of research design, from what mechanisms are studied to whether trials are powered to stratify results and identify effect modification. The authors identify institutional changes which need to be made in order to support this methodological reform as well as complementary research methods that may be employed to better understand “diversity issues that matter.”

Given that previous studies of inclusion in clinical trials have documents little progress in that regard, we applaud these authors for taking a far-reaching approach to the problem of diversity in clinical research. Their arguments are well-stated and the methodological and institutional approaches recommended herein are appropriate, straightforward and practical. We recommend publication with very minor grammatical/proof-reading changes.

Major Compulsory Revisions: None

Minor Essential Revisions:
1. 3rd page of body of paper, last line should read “we plead”
2. 5th page of body of paper, 2nd line, delete “to” (it’s redundant)
3. 5th page of body of paper, next sentence should read “What are the implications for clinical research methodology…” (delete “the”)
4. 5th page of body of paper, 3rd to bottom line, “retention” should be singular
5. 6th page of body of paper, 1st line, replace “to” with “the” (“anticipating the cultural and cognitive…”)
6. 6th page of body of paper, 4th line in first full paragraph, “outweighed” should be simply “weighed”

Discretionary Revisions: None

Level of interest: An article of outstanding merit and interest 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.