Reviewer's report

**Title:** Questioning participants in antimalarial and antiretroviral interaction trials to obtain adverse event, medical history and concomitant medication data: a mixed method study illustrating how responses are influenced by a trial's social context.

**Version:** 1  **Date:** 22 August 2013

**Reviewer:** Christopher J Colvin

**Reviewer's report:**

This is a very interesting and useful paper that looks at some of the challenges of collecting safety data during trials. It raises important concerns about how this data is collected and how comparisons across trials are (or are not) possible given varying data collection methods and the variety of factors that affect reporting and collection of this data.

I have no major concerns about the method, findings or ethics of the study and thus no major compulsory revisions. I did note a number of issues of language, interpretation and methodology description that are important to clarify. I have noted these in an annotated version of the manuscript PDF (attached) and I would consider these minor essential revisions.

In terms of discretionary revisions, it would be useful to have more descriptions of how the South African and Tanzanian contexts help explain some of the very interesting comparisons and contrasts made across the sites. And it would be useful to have more reference to the social science literature on trial communities, trial subjectivities, health citizenship, etc.

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

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

**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