Reviewer’s report

**Title:** When is informed consent required in cluster randomized trials in health research?

**Version:** 1  **Date:** 7 July 2011

**Reviewer:** Inmaculada de Melo-Martin

**Reviewer’s report:**

The purpose of this paper is to address the questions from whom, when, and how must informed consent be obtained in cluster randomized trials CRTs in health research. The authors use the moral purpose of consent –respect for persons-- as a conceptual foundation to answer those questions. The title and abstract are appropriately informative, the paper is clear, and the arguments are compelling. It provides a good overview of some of the main concerns that arise in relation to informed consent when conducting CRTs.

**Level of interest:** An article of importance 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.