Reviewer’s report

Title: Multi-site randomized controlled trial of fluoxetine in children and adolescents with autism (FAB): Rationale and design

Version: 1 Date: 9 May 2014

Reviewer: Sally Merry

Reviewer’s report:

This is an excellent and thorough protocol addressing the important issue of the effectiveness of fluoxetine in autistic spectrum disorder. The authors will conduct a rigorous trial that will address the limitations of previous studies on this topic. The study meets CONSORT guidelines. The aims are clear, the inclusion criteria well defined, there is a clear and credible primary outcome variable, the statistical analyses are appropriate, the study is adequately powered, randomisation processes ensure allocation concealment and adverse events will be monitored appropriately. No revisions are needed.

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