Reviewer's report

Title: Enrolling adolescents in HIV vaccine trials: Reflections on legal complexities from South Africa

Version: 1 Date: 1 April 2007

Reviewer: Linda-Gail Bekker

Reviewer's report:

General
This is a well written, readable and comprehensive paper written by South Africans outlining essential requirements for the lawful conduct of adolescent research in that country including compliance with consent requirements, child protection laws, and processes for the ethical and regulatory approval of research.
It gives a clear flavour of the expected complexities for researchers and research ethics committees, including determining that trial interventions meet current risk standards for child research. Explicit recommendations are made.
This article concludes with concrete steps for implementing these important trials in South Africa.
The paper has a strong SA bent, as suggested in the title, but is of interest globally as the question of involvment of adolescents in prevention research is currently debated and considered world wide. The fluidity, non-conformity and complexity of the SA legal and ethical landscape in this area is well noted and perhaps provides a backdrop for other countries to make comparisons of their various laws/guidelines. The recommendations have universal application and are useful as a checklist.
I thought hard but feel that the therapeutic/ non therapeutic aspect is sufficiently covered and is clear (or as clear as the law and guidelines allow)

Major Compulsory Revisions (that the author must respond to before a decision on publication can be reached)

I have no major revisions, other than to comment that obviously the legal situation is SA is in a state of flux and perhaps any updates particularly on the NHA regulations could be updated on review?

Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)

Only one error noted: ? confused sentence at the bottom of page 13/top page 14 'or a lack of tools....'.

Discretionary Revisions (which the author can choose to ignore)

nil

What next?: Accept after minor essential revisions

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 I have NO competing interests.