Reviewer's report

Title: The HAART Cell Phone Adherence Trial (WelTel Kenya1): A randomized controlled trial protocol [Trial Registration Number: NCT00830622]

Version: 3 Date: 6 August 2009

Reviewer: Gordon Doig

Reviewer's report:

Thank you for submitting this protocol to us. It is a novel and potentially important study. I wish you luck.

I suspect some form of 'blocking' was used during the generation of the random sequence. If not, it is theoretically possible, although unlikely, that one clinic could receive ALL intervention envelopes. One of the fundamental assumptions that allows us to pool data from multiple sites is that patients were randomised within each site. Could you please contact your project statistician to clarify this issue. Please report in your manuscript how you avoided this important theoretical severe imbalance issue.

If blocking was used, AND blocked sequences were provided to each site, you have 'stratified' randomisation by site. If so, please report in your manuscript.

Please report exactly which variables will be assessed for baseline balance and what decision rules will be used to determine whether balance was achieved or whether the variable will be offered to a multivariate model.

Sincerely,

Gordon S. Doig