Reviewer's report

Title: Feasibility study of a clinically-integrated randomized trial of modifications to radical prostatectomy

Version: 3 Date: 17 January 2012

Reviewer: Richard Platt

Reviewer's report:

Two items related to the changes deserve the editors attention:

Abstract: I recommend adding the underlined text, to make the abstract consistent with the full text: “Although recording by surgeons of the procedure used was incomplete (~80%), compliance with randomization was excellent when it was recorded, with fewer than 5% of procedures inconsistent with allocation.”

Page 7: The information about protocol deviations and failure to follow up is a worthwhile addition, especially the relative risks. However, the lack of statistical significance (see text below) does not provide evidence against failure of adherence to treatment assignment or loss to followup to cause important biases. To the extent the authors wish to make such an argument, a sensitivity analysis would be required.

Page 10. Everyone seems to agree on the importance of reducing the amount of missing data. Demonstrating that some conventional clinical trials have amounts of missing data similar to this study’s doesn’t advance that goal. Although this text was added in response to the reviews, it is worth considering whether the information is helpful to the overall evidence in favor of this trial design.

Also, I am unable to find the supplemental implementation guide the authors indicate they have provided.