Appendix B
Checklist for randomized clinical trial design

1 Selection description—clear portrayal of patients studied
2 Reject log—record of eligible population *not* accepted for the trial
3 Withdrawals—dropouts listed by diagnosis, treatment, and reason for withdrawal
4 Therapeutic regimens defined—includes timing, amount of daily therapies and all (additional) allowable therapies
5 Control regimen—placebo appearance and taste
6 Masking procedures
  a Randomization masking—unpredictability of upcoming treatment assignment
  b Masking of patients—therapy unidentified
  c Masking of physicians—therapy unidentified
  d Masking of physicians and patients—ongoing results of the trial are hidden
7 Testing procedures
  a Sizing the study—prior estimate of number of patients required (Δ, and risk levels α and β)
  b Distribution of pretreatment variables—known prognostic features by treatment category
  c Evaluation of masking—physicians and patients queried at the end of the study
  d Compliance—objective methods of verifying conforming behaviour of patients and physicians
  e Biological equivalent—attempt to measure therapeutic agent in its active form (after absorption or injection)
8 Statistical analysis
  a Statistical significance of end points—both test statistic and observed probability stated
  b β estimate—discussion of Type II error
  c Statistical inference—confidence limits, lifetable or time-series analysis, regression analyses or correlations
9 Handling of withdrawals—convention adopted for withdrawals
10 Side effects—report and discuss side effects of therapies
11 Retrospective analyses—post hoc analysis of results in sub-groups with due caution concerning conclusion
12 Masking of statistician—presentation of data to analyst in coded form.

13 Problem of multiple looks—consider influence of multiple analyses of accumulating data
14 Supplementary data
  a Dates of starting and stopping accessions
  b Results of pre-randomization data analysis—evaluation of baseline comparability of study groups
  c Tabulation of events employed as end-points for each treatment
  d Timing of events—event times (e.g. outcomes, withdrawals) given to permit construction of a plot of outcome against time

(Compiled by Chalmers and co-workers)