Statistical Review Check List

1. Do background and rationale clearly explain importance of study?
2. Will results have a clear and relevant interpretation and generalization?
3. Are specific aims clear, concise, and attainable?
4. Is study design clearly stated and appropriate to address specific aims?
   (a) Is patient population appropriate and clearly defined (inclusion/exclusion)?
   (b) Are there appropriate baseline and follow-up visits?
   (c) Are procedures at each visit clearly defined?
   (d) Is all necessary (and only necessary) data being collected?
   (e) Are there potential compliance or follow-up issues?
   (f) Are interim analyses and stopping rules appropriate?
   (g) Are evaluable patients clearly defined?
   (h) Can design be simplified?
5. Is there effective control of bias and confounding?
   (a) Is there a suitable population sampling design?
   (b) Is there a suitable control group?
   (c) Is there suitable randomization?
   (d) Is there suitable matching?
   (e) Is there suitable stratification?
   (f) Is there effective blinding?
6. Are primary and secondary hypotheses clearly stated and reasonable?
   (a) Will study design answer questions of interest?
   (b) Are outcome variables and covariates appropriate?
   (c) Is missing data accounted for correctly?
   (d) Are methods of analysis appropriate?
7. Is sample size calculation correct?
   (a) Is trial to determine difference or equivalence?
   (b) Is loss to follow up accounted for?
   (c) Are Type I and II error rates reasonable?
   (d) Are detectable differences clinically relevant?
   (e) Are there references for standard deviation, null proportion, etc.?
8. Is there appropriate data management and quality assurance?
9. Are there safety, informed consent, confidentiality, or ethical issues?