JOURNAL CLUB
EVALUATION QUESTIONS FOR ASSESSING CLINICAL RESEARCH REPORTS

While many of the following questions can be answered with a "yes" or "no" response, to be considered complete the rationale for your decision must be included.

Student Name: Date:
Rotation/Practice Site: Preceptor:

Journal, Title, Authors, Funding, Abstract
1. What is the journal's reputation?
   a. Is it peer-reviewed?

2. Is the title appropriate?
   a. Is it unbiased?
   b. Does it describe the trial sufficiently?

3. Are the researchers/authors qualified to do the trial?
   a. Degrees?
   b. Institutions/companies/affiliations?
   c. Has the lead author published other papers in this area?
   d. Was a statistician involved?

4. Who funded the trial?
   a. How does the funding affect your conclusions?

5. Is the abstract appropriate?
   a. Is it structured or unstructured?
   b. Is all of the pertinent information included?

Introduction
6. Is the introduction appropriate?
   a. Did the authors describe all pertinent previous research?
   b. Did they state why the trial was done?

7. Was the objective or hypothesis clearly stated and appropriate?
a. Does it reflect the methodology?

Methods

Subjects
8. How many subjects were studied?
9. How many centers were involved?
10. Were the inclusion criteria clearly stated and appropriate?
   a. Was the disease defined clearly and appropriately?
11. Were the exclusion criteria clearly stated and appropriate?
   a. Can you identify why each exclusion criterion was made?
12. How were the subjects recruited?
   a. How does that affect the results?
13. Was the protocol approved by an Investigational Review Board (IRB)?
14. Did subjects give informed consent?

Treatment
15. Were subjects randomly assigned to the groups?
   a. Was the randomization procedure truly random?
16. Were the controls appropriate?
   a. Placebo, active or historical controls?
17. Were the drug doses appropriate?
18. Was the design parallel or crossover?
   a. Was a placebo run-in used?
   b. If crossover, was an appropriate wash-out period used?
19. Was the study blinded or open-label?
   a. If blinded, who was blinded?

Measurements
20. Were the measurements appropriate?

21. Who took the measurements?
   a. If a multi-center study, were steps taken to assure that the measurements were done the same in all centers?
   b. Were those who took the measurements blinded?

22. Was the duration of the trial sufficient?

23. Was adherence/compliance assessed?

24. Were the endpoints appropriate?
   a. Were surrogate endpoints used?

Statistics
25. Was a power analysis done?
   a. What p-values was considered statistically significant?
   b. What power was used?
   c. Did the authors anticipate drop-outs?
   d. How many subjects were needed for statistical conclusions to be made?

26. Were the statistical tests appropriate?
   a. How many groups were assigned?
   b. Were the data for each endpoint nominal, ordinal or continuous?
   c. Were the data normally or not-normally distributed (often not stated)?

27. Were the statistical tests one-tailed or two-tailed?
   a. What does that mean?

28. Was an intention-to-treat or per-protocol analysis performed?
   a. What does that mean?
   b. How does that affect your interpretation of the results?

Results
29. Were the groups equally matched after randomization?
a. If not, was one group more likely to do better or worse?

30. Were the results presented clearly and accurately?
   a. Were there any table, graph or statistical distortions?

31. Were all the results presented?

32. Were all drop-outs accounted for?

33. Was this an interim analysis?
   a. If so, how does that affect your conclusions?

34. Were subgroup analyses done?
   a. Were there enough patients in each subgroup for statistical conclusions to be made?
   b. Did the authors state in the methodology that they were going to do a subgroup analysis?

35. Were differences statistically significant and/or clinically important?

36. Were numbers needed to treat (NNT) provided in the study?
   a. If not, are you able to calculate them from the data provided?
   b. How does the NNT data affect your conclusions?

Discussion, Conclusions, References

37. Did the authors compare the results of the trial to the results of similar previous trials?
   a. Did they explain any differences found?

38. Did the authors discuss the limitations of the trial?
   a. Did they explain how the limitations might have affected the results?

39. Were valid conclusions drawn?
   a. Were they based on the objective, methods and results?

40. Was the trial referenced with appropriate literature?
   a. Did the authors include all pertinent previous trials?
   b. Are the references up-to-date?
c. Did the authors cite themselves excessively?

41. Who should the trial results be applied to?

THE ULTIMATE QUESTIONS

42. Are the results of the study valid?

43. What were the results?

44. Will the results help in caring for my patients?