**Scientific Review Checklist**

**Scientific Critique:**

a. Hypothesis statement **Y N**

b. Protocol sound - appropriate to get information being sought **Y N**

c. Methods sound - appropriate to reach conclusions **Y N**

d. Inclusion & exclusion criteria listed **Y N**

e. Patient safety issues **Y N**

f. IRB protocol is consistent with grant or sponsor’s document **Y N**

g. Problems - please note below:

**Statistics:**

Sample size/power calculation **Y N N/A**

 Statistical analysis appropriate **Y N N/A**

**Consent:**

Does it match IRB protocol **Y N**

Inclusion & exclusion criteria **Y N**

Are the risks laid out appropriately **Y N**

**Women, minority and children:**

Are any of these classes excluded **Y N**

If yes, are the exclusions scientifically supported and appropriate **Y N**

**Data and Safety Monitoring Plan:**

Is a DSMP presented and adequate **Y N**

If no, suggested revisions must be listed

**Please rate your evaluation by circling your score below:**

Outstanding

Excellent

Very Good

Good

Acceptable

Unacceptable

Problems noted: