Reviewer Name:

Review Date:

Protocol Title:

Principal Investigator:

Protocol Version Number & Date:

Review Type:  Initial Protocol Review

Resubmission to Full Committee

Protocol Amendment Review

Sponsor:

-----------------------------------------------------------

**Statistical Synopsis:**

Statistical design:

Is the statistical design appropriate?  Yes

No

Comments:

Hypothesis/Endpoints:

Are the hypothesis and endpoints appropriate?  Yes

No

Comments:

Sample size calculation/power:

Is the sample size calculation/power appropriate?  Yes

No

Comments:

Interim analyses/stopping rules, if relevant:

If needed, are stopping rules/interim analysis satisfactory?  Yes

No

Comments:

Statistical analysis plan:

Is the statistical analysis plan satisfactory?  Yes

No

Comments:

Other Comments:

### ----------------------------------------------------

**Scientific Score** (no decimals, please):

Scoring Scale: Enter a numeric score from 1 - 9, one (1) being the

best and nine (9) being the worst. Assign a whole number to score in terms of relative importance in executing a successful trial. This score will be used to guide the Site Committee in selecting the Final Overall Score, which in turn will guide Site Committee prioritization. See last page for additional guidance.

List of Concerns that Must be Addressed Before Approval

Suggestions (response not required)

### ----------------------------------------------------

**Recommendation:**

**Approval**

**Deferred for Revision**

**Disapproval**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Statistical Reviewer’s Signature Date

**Scientific Scoring Scale**

|  |  |  |
| --- | --- | --- |
| **Score** | **Descriptor** | **Additional Guidance on Strengths/Weaknesses** |
| **1** | **Exceptional** | Exceptionally strong with essentially no weaknesses |
| **2** | **Outstanding** | Extremely strong with negligible weaknesses |
| **3** | **Excellent** | Very strong with only some minor weaknesses |
| **4** | **Very Good** | Strong but with numerous minor weaknesses |
| **5** | **Good** | Strong but with at least one moderate weakness |
| **6** | **Satisfactory** | Some strengths but also some moderate weaknesses |
| **7** | **Fair** | Some strengths but with at least one major weakness |
| **8** | **Marginal** | A few strengths and a few major weaknesses |
| **9** | **Poor** | Very few strengths and numerous major weaknesses |
| **Minor Weakness:** An easily addressable weakness that does not substantially lessen the impact  **Moderate Weakness:** A weakness that lessens the impact  **Major Weakness:** A weakness that severely limits the impact | | |