Cancer Center Protocol Number:

Protocol Title:

Secondary Reviewer:

Review Date:

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### PROTOCOL CRITIQUE

Are the primary and secondary **objectives** scientifically sound?  Yes

No

Comments:

Is the study **design** appropriate to meet the objectives?  Yes

No

Comments:

Do you have any comments or questions concerning the **statistical plan** (sample size, planned analysis, etc.)?  Yes

No

Comments:

Does the **science** justify the risks to the patient?  Yes

No

Comments:

1. **SCIENTIFIC REVIEW SCORING**

Is the Final Overall Score from the Program Site Committee(s) appropriate?

Yes

No

Comments:

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

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

Scoring Scale: Enter numeric score from 1 - 9, 1 being the best and 9 being the

worst (refer to Appendix 1).

1) Clinical Importance

2) Trial Design

3) Innovation/Science

4) Statistics

5) DSMP

6) Competing Trials

7) Accrual/Feasibility

**Final Scientific Score** (not an average)

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1. **REVIEW OUTCOME**

Concerns that Must be Addressed Before Approval (must accompany Disapproval or Contingent Approval; cannot accompany Approval)

Helpful Considerations or Suggestions (may accompany Disapproval, Contingent Approval, or Approval)

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

**Recommendation:**

**Approval**

**Contingent Approval**

**Disapproval**

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Secondary Reviewer’s Signature Date

1. **APPENDICES**

**Appendix 1: 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 | | |