Cancer Center Protocol Number:

Protocol Title:

Biostatistician:

Review Date:

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**Biostatistician Disclaimer**

I was involved in the initial development/design of this protocol [ ]  Yes

 [ ]  No

### PROTOCOL CRITIQUE

**Objectives:**

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

 [ ]  No

Comments:

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

 [ ]  No

If No, please comment:

**Study Design:**

If the study design is not satisfactory, please suggest how it might be improved to better achieve the objectives:

Is the study design sufficient to answer the statistical question? [ ]  Yes

 [ ]  No

### STATISTICAL DESIGN SYNOPSIS

Describe the statistical design:

Describe the endpoints:

Describe the sample size calculation/power:

Describe the interim analyses/stopping rules:

**Statistical Design Comments:**

Is the statistical design appropriate? [ ]  Yes

 [ ]  No

 Comments:

Are the endpoints adequate? [ ]  Yes

 [ ]  No

 Comments:

Is the sample size calculation/power sufficient? [ ]  Yes

 [ ]  No

 Comments:

Additional comments concerning the statistical design:

**Analysis Plan:**

Describe the planned analyses:

Are the planned analyses appropriate? [ ]  Yes

 [ ]  No

Comments:

1. **SCIENTIFIC REVIEW SCORING**

**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).

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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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Biostatistician 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 |