**Scientific Reviewer Committee (SRC) Biostatistician Reviewer Form**

**Protocol Number: Protocol Version Date:**

**Date Sent to Reviewer: 10.12.17 Reviewer Name:**

|  |  |
| --- | --- |
| **STUDY DESIGN AND RATIONALE** | |
| **1.0 Is the type of study (e.g., Pilot, Phase I, Phase II, Phase III)**  **accurately described throughout the protocol (Title, Background, Design, etc)?** | **Y or N?** |
| **Comments: If marked N, comments must be provided:** |  |
| **2.0 Is the study design appropriate for the study objectives?** | **Y or N?** |
| **Comments: If marked N, comments must be provided:** |  |
| **3.0 Are the statistics used in the design process and reported in the**  **protocol appropriate?** | **Y or N?** |
| **Comments: If marked N, comments must be provided:** |  |
| **4.0 Does this study adequately address power and sample size?** | **Y or N?** |
| **Comments: If marked N, comments must be provided:** |  |
| **5.0 Is the proposed analysis appropriate for addressing protocol objectives?** | **Y or N?** |
| **Comments: If marked N, comments must be provided:** |  |
| **6.0 Are there sufficient plans in place to collect and analyze the data obtained in this study?** | **Y or N?** |
| **Comments: If marked N, comments must be provided:** |  |

Using the NIH CSR Merit descriptors (see below), please provide your score of the scientific impact of the trial you reviewed: The scores are then averaged and the result multiplied by 10 to determine the final impact/priority score (range of 10 to 90).

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

Reviewer Rating: SRC votes: The SRC review process has the following possible outcomes:

1. **Approved.** Comments or suggestions may be included in the approval letter, and incorporated into protocol and should be followed-up on as is necessary, but no formal response to SRC is required.
2. **Approved with contingencies.** Response and/or Revisions required prior to approval, confirmation of response/revisions required.

**2a)** The review of responses and/or revisions may be conducted administratively, by the Chairs.

**2b)** The individual reviewer(s) that requested the response/revision must confirm the responses and/or revisions.

1. **Hold for re-review.** Substantial revisions to the protocol are required. The full committee must re-review this study at another SRC meeting.
2. **Reject.** There are fundamental flaws in the study, the study does not align with Lurie Cancer Center priorities, or it is not feasible to conduct the study. The study may not move forward.

|  |  |
| --- | --- |
| **Reviewer Score: 1-9** |  |
|  |  |
| **Reviewer Rating: (either 1, 2A, 2B, 3, or 4)** |  |
| **Comments regarding score or rating:** |  |