**Scientific Reviewer Committee (SRC) Primary/Secondary Reviewer Form**

**Protocol Number: Protocol Version Date:**

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

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| **STUDY DESIGN AND RATIONALE** | |
| **1.0 Are the objectives and the underlying hypothesis clearly stated?** | **Y or N?** |
| **Comments: If marked N, comments must be provided:** |  |
| **2.0 Are the questions to be addressed important?** | **Y or N?** |
| **Comments: If marked N, comments must be provided:** |  |
| **3.0 Is adequate scientific rationale provided to support the proposed study?** | **Y or N?** |
| **Comments: If marked N, comments must be provided:** |  |
| **4. Does the background adequately explain how the proposed research fits into the current trends of research?** | **Y or N?** |
| **Comments: If marked N, comments must be provided:** |  |
| **5. Does the proposed design address the objectives and scientific**  **rationale?** | **Y or N?** |
| **Comments: If marked N, comments must be provided:** |  |
| **6. Are the eligibility criteria adequately describing the relevant study**  **population? Are the criteria objectively measurable or obtainable?** | **Y or N?** |
| **Comments: If marked N, comments must be provided:** |  |

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| **STUDY FEASIBILITY & PRIORITIZATION** | |
| **Annual Accrual Goal:** |  |
| **Projected time to completion:** |  |
| **Identified Competing studies (per DT Endoresment Form/ and DT research profile) Studies:** |  |
| **7. Is the design feasible within the resources of Robert H. Lurie Comprehensive Cancer Center? If not, are there contingency plans to make certain sufficient resources available to meet the objectives of the research? Will there be sufficient resources, *including patients,* to complete the proposed research within an acceptable time frame?** | **Y or N?** |
| **Comments: If marked N, comments must be provided:** |  |
| **8. If competing studies have been identified, are they prioritized appropriately?** | **Y or N?** |
| **Comments: If marked N, comments must be provided:** |  |
| **Safety & Monitoring** | |
| **Is the proposed research safe? Are there sufficient safeguards in the proposal to ensure safety?** | **Y or N?** |
| **Comments: If marked N, comments must be provided:** |  |
| **Is there a data and safety monitoring plan appropriate to the level of risk to research subjects?** | **Y or N?** |
| **Comments: If marked N, comments must be provided:** |  |
| **Is there a description of the mechanism of adverse event reporting and grading?** | **Y or N?** |
| **Comments: If marked N, comments must be provided:** |  |
| **Is/are the dose(s) of the drug(s) appropriate?** | **Y or N?** |
| **Comments: If marked N, comments must be provided:** |  |
| **Does the protocol provide dose reductions and are they reasonable?** | **Y or N?** |
| **Comments: If marked N, comments must be provided:** |  |
| **Do the selection criteria address potential adverse effects and drug interactions?** | **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.

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