

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

**Protocol Number: Protocol Version Date:**

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

|  |
| --- |
| **DRUG INFORMATION**  |
| **Is the background on the study drug provided? This includes:****- Mode of action, PK/PD** **- Drug-drug interactions** **- Possible side effects** | **Y or N?** |
| **Comments: If marked N, comments must be provided:**  |  |
| **Is the Pharmacy manual or information on drug dispensing available? This includes:****- Drug storage/stability** **- Preparation****- Drug ordering**  | **Y or N?** |
| **Comments: If marked N, comments must be provided:**  |  |
| **Is the information on drug administration available and appropriate? Including:****- Dosage, route, treatment duration****- How to take the drug (with food or empty stomach)** **- Monitoring after administration**  | **Y or N?** |
| **Comments: If marked N, comments must be provided:**  |  |
| **Is the source of the study drug clear (commercial or investigational supply)?** **If the drug is commercially available, is the information in the protocol consistent with the package insert information and the NM pharmacy standards? If it is not consistent with the package insert, is justification for the difference provided in the protocol, pharmacy manual, or IB?** | **Y or N?** |
| **Comments: If marked N, comments must be provided:**  |  |
| **Are permitted and prohibited drugs before and/or during the trial specified in the protocol and if the selection appropriate? This also includes****- Allowed rescue or pre-medications,****- Prophylactic medications****- “Wash-out” period for any medications** | **Y or N?** |
| **Comments: If marked N, comments must be provided:**  |  |

|  |
| --- |
| **STUDY FEASIBILITY & PRIORITIZATION** |
| **Does the study require investigational pharmacy services (e.i. product storage, preparation)?** | **Y or N?** |
| **Is the study feasible within the resources of NM investigational pharmacy, including study drug preparation, storage, etc.? If not, are there contingency plans to make certain sufficient resources available?**  | **Y or N?** |
| **Comments: If marked N, comments must be provided:**  |  |
| **Does the study require shipment or transport of study drug to sub-sites or NM affiliates?** | **Y or N?** |
| **Comments: If marked Y, comments must be provided:**  |  |
| **Does the study involve control substance study drug(s)? If so, will the drug be given on- site or outpatient (send home with the patient)?** | **Y or N?** |
| **Comments: If marked Y, comments must be provided:**  |  |
| **Does the study involve biohazardous drug(s)? If so, does the study need to be reviewed by IBC committee?**  | **Y or N?** |
| **Comments: If marked Y, comments must be provided:**  |  |
| **Safety & Monitoring**  |
| **Is the proposed research safe from the pharmacy standpoint? Are there sufficient safeguards and monitoring in the proposal to ensure patient safety?** | **Y or N?** |
| **Comments: If marked N, comments must be provided:**  |  |
| **Does the protocol provide dose modification criteria and are they reasonable? Is there a mechanism of adverse event reporting** | **Y or N?** |
| **Comments: If marked N, comments must be provided:**  |  |
| **Does the selected dosage account for study drug interactions? (i.e. study drug- study drug interactions AND study drug- home medication 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.

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