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| **Date of Review** |  |
| **Reviewer Name** |  |
|  |  |
| **JeffTrial#** |  |
| **Principal Investigator** |  |
| **Protocol Title** |  |

# Study Summary

Please describe the objectives of the proposed study, the patient population, type of therapy, and the scientific rationale or basis for conducting the study. Please limit your response to a half page and DO NOT cut and paste from the protocol.

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# Scientific Review

Are the primary and secondary objectives scientifically sound?  Yes No

Please comment.

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Is the study design appropriate to meet the objectives?  Yes No

Please comment.

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Will the data collected provide information to answer the research question?  Yes No

Please comment.

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Please rate scientific merit:  Low  Medium  High

Please describe any questions or comments you have regarding the background and rationale, study methodology, study design, eligibility criteria.

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# Feasibility

Are there competing protocols for the same patient population?  Yes No

If yes, do you have any concerns with how the MDG has prioritized the studies? Please explain.

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Is rare status requested for this patient population?  Yes No

If yes, do you approve it?  Yes No

Please comment.

Based on the Protocol Facilitation Committee’s report, do you have any further concerns about how the study is financed, potential conflicts of interest, or ability to complete the trial in a timely manner?

Yes No

Please comment.

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Is the study being planned to open at other controlled entity / network sites of Jefferson?  Yes No If yes, do you have any concerns about opening the study at other sites based on the MDG and Facilitation committee documents submitted for those sites? Please comment.

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Based on the above criteria, is the study feasible?  Yes  No

# Data and Safety Monitoring

Is there an appropriate Data and Safety Monitoring Plan for the trial?  Yes No

If not, please explain.

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Is there an interim analysis for safety/efficacy?  Yes No

Please comment.

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Are there formal stopping rules?  Yes No

Please comment.

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# Inclusion of Women and Minorities

Is there an appropriate plan for the inclusion of women and minorities?  Yes No

Please comment.

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# Outcome

Overall ranking of priority within SKCC:  Low  Medium  High

Concerns to be addressed before the study should be approved.

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Other comments.

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**Preliminary recommendation:**  Approve

Contingent Approval

Defer

Disapprove