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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