PRMC Full Review: Clinical

**Protocol Number: Enter H-number**

**Reviewer Name: Enter name**

## Recommended Scores

What is the study priority for the DLDCCC? Choose an item.

Scientific Merit? Choose an item.

## Study Design

1. Are the objectives clearly stated? Choose an item.

2. Does the background justify the reasons for conducting this study
(e.g., is there sound scientific rationale)? Choose an item.

3. Is the study design appropriate to answer questions posed by
the objectives? Choose an item.

4. Does the plan ensure adequate accrual to answer the
questions posed? Choose an item.

## Implementation:

1. Can the protocol logistically be implemented at this institution? Choose an item.

2. Is study accrual/completion feasible within the stated time frame? Choose an item.

3. Are the eligibility (inclusion/exclusion) criteria clear? Choose an item.

4. Are the on-study/patient registration procedures clear? Choose an item.

5. Is the definition of course length clear in the protocol? Choose an item.

6. Are the reporting requirements clear? Choose an item.

7. Are the response criteria appropriate and consistent with the
study objectives? Choose an item.

8. Are all tissue banking issues addressed? Choose an item.

9. Are the toxicity criteria appropriate and consistent with the
study objectives (including definitions of DLT or MTD if appropriate)? Choose an item.

10. If the protocol involves both study agent(s) and non-study agent(s),
is it clear whether AEs will be reported for both agents
or only for the study agent(s)? Choose an item.

11. Can the anticipated personnel requirements for Research Nurse/Coordinator, Pharmacy,
and Data Management be met? Choose an item.

## Data and Safety Monitoring: Choose an item.

## Recommended Action: Choose an item.

## Reviewer Comments:

Please provide your review summary AND any questions to the PI, if the action is Approved with Modifications or Tabled.

Click or tap here to enter text.