Cancer Center Protocol Number:

Protocol Title:

Primary Reviewer:

Review Date:

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1. **STUDY SUMMARY**

**Please summarize the key components of the study (relevant background information, study objectives and design, key eligibility criteria, treatment regimen, treatment-related procedures, and any safety issues), limiting your response to the space below.**

### DISEASE SITE COMMITTEE REVIEW CRITIQUE

Are there competing protocols for this same patient population?  Yes

No

If yes, have they been appropriately prioritized at disease site committee, and

how?

Have all feasibility issues been appropriately addressed at the disease site committee?  Yes

No (if no, please comment)

General Comments (e.g., how financed, potential conflicts, appropriate co-investigators, time to completion, and comments on above):

### PROTOCOL CRITIQUE

Are the primary and secondary **objectives** scientifically sound?  Yes

No

Comments:

Is the study **design** appropriate to meet the objectives?  Yes

No

Comments:

Do you have any comments or questions concerning the **statistical plan** (sample size, planned analysis, etc.)?  Yes

No

Comments:

Does the **science** justify the risks to the patient?  Yes

No

Comments:

1. **DATA SAFETY MONITORING**

For *institutional* studies only, please identify Risk Level (refer to Appendix 1):

**High:**  Institutional Phase 1 therapeutic

Institutional therapeutic using gene therapy or vaccines

**Moderate:**  Institutional Phase 2 therapeutic

Institutional Phase 3 therapeutic

**Low**

For *all* studies, please indicate the following:

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Yes** | **No (please comment below)** | **Not applicable/ necessary** |
| Is there a Data Safety Monitoring Committee (DSMC) and/or appropriate DSM plan? |  |  |  |
| Is there an interim analysis for safety/efficacy? |  |  |  |
| Are there formal stopping rules? |  |  |  |
| Based on the above: Does the protocol adequately incorporate an appropriate level of monitoring and surveillance? |  |  |  |

Comments:

1. **ACCRUAL OF CHILDREN, WOMEN, AND MINORITIES**

|  |  |  |  |
| --- | --- | --- | --- |
| **Is there an appropriate plan for the inclusion of:** | **Yes** | **No** | **N/A** |
| Children (subjects under the age of 21) |  |  |  |
| Women |  |  |  |
| Minorities |  |  |  |

Comments on any of the above:

1. **SCIENTIFIC REVIEW SCORING**

Is the Final Overall Score from the Program Site Committee(s) appropriate?

Yes

No

Comments:

### ----------------------------------------------------

**Scientific Score** (no decimals, please):

Scoring Scale: Enter numeric score from 1 - 9, 1 being the best and 9 being the

worst (refer to Appendix 2).

1) Clinical Importance

2) Trial Design

3) Innovation/Science

4) Statistics

5) DSMP

6) Competing Trials

7) Accrual/Feasibility

**Final Scientific Score** (not an average)

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1. **REVIEW OUTCOME**

Concerns that Must be Addressed Before Approval (must accompany Disapproval or Contingent Approval; cannot accompany Approval)

Helpful Considerations or Suggestions (may accompany Disapproval, Contingent Approval, or Approval)

### ----------------------------------------------------

**Recommendation:**

**Approval**

**Contingent Approval**

**Disapproval**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Primary Reviewer’s Signature Date

1. **APPENDICES**

**Appendix 1: Data and Safety Monitoring Risk Level Table**

|  |  |  |  |
| --- | --- | --- | --- |
| **Risk**  **Assignment** | **Study Type** | **Monitoring** | **Surveillance** |
| **High** | Institutional Phase 1  therapeutic | Monitor all subjects  once a month as subjects are enrolled/ monitor through DLT period | Real time monitoring  of AEs and SAE's weekly at site committees; DSMC monitors SAE every six weeks |
| **High** | All Institutional  therapeutic using gene therapy or vaccines regardless of phase | Monitor once a  month as subjects are enrolled/ monitor first three  treatments/cycles | Real time monitoring  of AEs and SAEs weekly at site committees; DSMC monitors SAE every six weeks |
| **Moderate** | Institutional Phase 2  therapeutic | Monitor twice a year  at 20% of subjects enrolled in the six months prior to monitoring visit | Real time monitoring  of AEs and SAEs monthly at site committees; DSMC monitors SAE every six weeks |
| **Moderate** | Institutional Phase 3  therapeutic | Monitor 20% of  yearly accrual during the calendar year that monitoring visit occurs | Real time monitoring  of AEs and SAEs monthly at site committees; DSMC monitors SAE every six weeks |
| **Low** | Behavioral studies/  early detection or diagnostic | No routine  monitoring unless requested by PI or 2 or more SAEs with attribution to study procedures in a six month period of time | DSMC monitors for  SAEs every six weeks |

**Appendix 2: Scientific Scoring Scale**

|  |  |  |
| --- | --- | --- |
| **Score** | **Descriptor** | **Additional Guidance on Strengths/Weaknesses** |
| **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 |
| **Minor Weakness:** An easily addressable weakness that does not substantially lessen the impact  **Moderate Weakness:** A weakness that lessens the impact  **Major Weakness:** A weakness that severely limits the impact | | |