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