Reviewer Name:

Review Date:

Protocol Title:

Protocol Version Number:

Protocol Version Date:

UCSF Principal Investigator:

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**UCSF Involvement** *(Please select only one):*

[ ]  Investigator-Initiated: Single Center

[ ]  Investigator-Initiated: Multicenter – UCSF is lead site

[ ]  Investigator-initiated: Multicenter – other center or community organization is lead site

[ ]  National (Cooperative) Group

[ ]  Other:

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

**What organization has performed peer-review?**

**Has the project been funded?** [ ]  Yes [ ]  No

**If Yes, start date for funding:**

Data Management Resources Adequate/Available? [ ]  Yes [ ]  No

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

**Operational Feasibility Review:**

**Expected Accrual *Total*:**       **Expected *Annual* Accrual:**

***REMINDER:*** *If annual accrual goals are below 5 (or below 3 for National/Cooperative Group), an accrual* ***waiver*** *needs to be submitted to the PRMC Administrator (template available upon request)*

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**Operational Feasibility Review, continued**:

**Comments Yes No N/A**

Eligibility criteria are appropriate [ ]  [ ]  [ ]

and designed to meet enrollment

targets

Visit schedules/times and duration [ ]  [ ]  [ ]

of participation are feasible for both

patients and study personnel

Any special personnel required for [ ]  [ ]  [ ]

this study have been addressed

(e.g. subspecialists, technicians, etc.)

Sufficient support staff available [ ]  [ ]  [ ]

for study completion

Study can be completed in [ ]  [ ]  [ ]

reasonable timeframe

Please list here any other factors that may influence the operational feasibility of this protocol:

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

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

Scoring Scale: For each category below, enter numeric score from 1 - 9, one (1) being the

 best and nine (9) being the worst. See last page for additional guidance.

1) Clinical Importance

2) Study Design

3) Innovation/Science

4) UCSF Involvement in Development

 (include career development/grant component)

5) Potential for UCSF Publication

6) Accrual/Feasibility

Now, assign a whole number that merges all preceding category scores in terms of relative importance in executing a successful trial; *do not* average the preceding scores. Your overall score will be used to guide the Site Committee in selecting the Final Overall Score, which in turn will guide Site Committee prioritization.

**Overall Score** (not the average)

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

List of Concerns that Must be Addressed Before Approval [ ]  None

(if there are Concerns, Recommendation must be Concerns sent to PI)

Suggestions (response not required) [ ]  None

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

**This study is deemed feasible with reasonable prioritization.**

**Recommendation:**

**[ ]  Approval**

**[ ]  Concerns sent to PI** (Concerns must be addressed prior to approval)

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Reviewer Signature Date

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

Responsible Site Committee or Working Group

**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 |