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 | | |