Reviewer Name:

Review Date:

Protocol Title:

Protocol Version Number:

Protocol Version Date:

Review Type:  Initial Protocol Review

Resubmission to Full Committee

Protocol Amendment Review

UCSF Principal Investigator:

Sponsor:

Source(s) of Funding:

Is Funding Adequate?  Yes

No

Unknown

Data Management Resources

Adequate/Available?  Yes

No

-----------------------------------------------------------

**Phase of Study: UCSF Involvement** *(Please select only one):*

Compassionate/Emergency Use  Investigator-Initiated: Single Center

Pilot/Feasibility  Investigator-Initiated: Multicenter – UCSF or Affiliate is lead site

Phase I  Investigator-initiated: Multicenter – other center is lead site

Phase I/II Disease-Specific  National (Cooperative) Group

Phase I/II Non-Disease-Specific  Industry: Single Center

Phase II  Industry: Multicenter – Significant UCSF or Affiliate Input on

Phase II/III Design/Reporting

Phase III  Industry: Multicenter – No UCSF or Affiliate Input on

Phase IV Design/ Reporting

N/A  Other:

-----------------------------------------------------------

**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.**

**ACCRUAL CONSIDERATIONS**

**List Competing Trials (what is relative priority of this trial?):**

Section includes information provided by CRNO

**Expected *UCSF* Accrual *Total*:**        N/A **Expected *UCSF* *Annual* Accrual:**        N/A

**Expected *Affiliate* Accrual *Total*:**        N/A **Expected *Affiliate* *Annual* Accrual:**        N/A

**Provide a rationale for how the above Target Accrual figures were determined:**

Based on Current Patient Population/Tumor Registry Data

Previous Accrual for Similar Protocol(s)

Did previous protocol(s) successfully complete enrollment?

Yes

No

Not Applicable (e.g., study is still enrolling)

Other:

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

**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) Trial 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

Suggestions (response not required)

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

**Recommendation:**

**Approval**

**Deferred for Revision**

**Disapproval**

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

Expedited Reviewer’s Signature Date

**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 | | |