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This form should ***only*** be used when PRC requests Site Committee input –

do not use for every amendment submission

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Chair or Co-Chair Name:

Review Date:

Protocol Title:

Protocol Version Number & Date:

Sponsor:

Principal Investigator:

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**Statement of Changes:**

Provide a brief description of the substantive changes in this protocol amendment:

**Operational Feasibility Review -- Accrual**

Does this amendment impact the overall or annual accrual goals? [ ]  Yes [ ]  No

**If Yes**, please provide the new targets:

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

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**Operational Feasibility Review -- Continued:**

 **Yes No N/A Comments**

Eligibility criteria are appropriate [ ]  [ ]  [ ]

and designed to meet enrollment

targets

Any special pharmacy requirements [ ]  [ ]  [ ]

have been addressed

Any special imaging requirements [ ]  [ ]  [ ]

have been addressed

Any special pathology requirements [ ]  [ ]  [ ]

have been addressed

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

**Operational Feasibility Review, continued**:

 **Yes No N/A Comments**

Is this an investigator-initiated study? [ ]  [ ]

**If Yes**, There is sufficient [ ]  [ ]  [ ]

 financial commitment to

adequately conduct the trial

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

**----------------------------------------------------**

Concerns that Must be Addressed before Approval

1)

2)

3)

4)

5)

6)

7)

8)

9)

10)

Suggestions (response not required)

1)

2)

3)

4)

5)

6)

7)

8)

9)

10)

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**Study Disposition:**

**[ ]  Approval**

**[ ]  Deferred for Revision**

[ ]  **Disapproval**

**By signing below, I assert that the protocol remains scientifically valid, relevant, and logistically feasible given the changes in this protocol amendment.**

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

Chair or Co-Chair Signature Date

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Responsible Site Committee