Chair or Co-Chair Name:

Responsible Site Committee:

Review Date:

Protocol Title:

Protocol Version Number:

Protocol Version Date:

Review Type:  Initial Protocol Review

Transfer Study – Initial Review

Resubmission to Full Committee

Protocol Amendment Review

Review Pertains To:  UCSF Site(s)

(check *all* that apply)  [HDFCCC Family](https://wiki.library.ucsf.edu/display/HDIRC/HDFCCC+Institutional+Family+and+Outside+Affiliate+Institution+Data+Management+for+NCI+Accrual+Reporting) Site(s)

[HDFCCC Affiliate](https://wiki.library.ucsf.edu/display/HDIRC/HDFCCC+Institutional+Family+and+Outside+Affiliate+Institution+Data+Management+for+NCI+Accrual+Reporting) Site(s)

International Site(s)

List all non-UCSF Site(s):

UCSF Principal Investigator:

Sponsor:

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**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:

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**UCSF or Affiliate Investigator-Initiated Trial (IIT) Protocol Development:**

Section includes information provided by CRNO

1. Is this a UCSF-controlled or Affiliate-controlled IIT protocol?  Yes  No

***If question 1 was answered No, please skip down to Operational Feasibility Review.***

1. Is this UCSF or Affiliate IIT protocol on the appropriate HDFCCC protocol template or was it edited to include all mandated elements from the HDFCCC protocol template?

Yes  No  Unknown  Not Applicable

1. Was a trained statistician consulted on the protocol design, and are they listed on the protocol’s face page?

Yes  No  Unknown  Not Applicable

1. If there are unique or special requirements, has Investigational Drug Service (IDS) been consulted?

Yes  No  Unknown  Not Applicable

1. Does the protocol adequately address equitable participant recruitment strategies?

Yes  No  Unknown  Not Applicable

1. Does the protocol include appropriate multi-center language?

Yes  No  Unknown  Not Applicable (single-center)

7) Does the protocol include an international component?

Yes  No  Not Applicable

A) *If Yes*, has the PI notified the Global Cancer Program?

Yes  No  Unknown

***\*\* STOP! If any of questions 2-6, or question 7A, were answered No or Unknown, the Chair/Co-Chair must give the protocol a Study Disposition of Deferred for Revision and add the item to Concerns that Must be Addressed before Approval (below) and require a documented response before issuing full approval. \*\****

***NOTE: Please remind the PI that they are required to share the final version of the protocol with the DSMC Director prior to submission to PRMC.***

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**Operational Feasibility Review:**  Section includes information provided by CRNO

1) Has the PI completed the HDFCCC Mandated PI Training Course?

Yes  No  Unknown

1A) If No or Unknown, has the DSMC been notified?

Yes  No  Unknown

***If question 1A above is answered No or Unknown, the Chair/Co-Chair must hold approval until the appropriate entities have been notified***

2) Is the study already Open/Accruing at other site(s)? Yes  No  Unknown

2A) If yes, what is the current overall accrual and expected date of study-wide enrollment completion:

Unknown

3) Does UCSF or Affiliate plan to participate in all

parts/stages/arms of the study? Yes  No

3A) If No, please specify which parts/stages/arms here:

4) For non-Industry studies, does this protocol include multiple diseases, or participants at different stages of disease progression, where Standard of Care (SOC) may be different?

Not Applicable – This is an Industry protocol

Not Applicable – This is a protocol amendment review

No- single disease state where SOC will not differ

Yes – please **list the top five** disease or cohorts of participants**\*** that are likely to be accrued to:

**\*** Cohort of participants = a group of participants where the SOC may be different, e.g., participants with or without metastases.

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**Operational Feasibility Review, continued:**  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

***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)*

**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:

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

**Operational Feasibility Review, continued:**

1. Separate list of prioritization of studies under development prepared

Yes (*required for all initial reviews*)

No – This is a transfer study already Open to Accrual

No – This is a protocol amendment review (*e.g., Adaptive Amendment/Platform Protocols*)

1. Are there any competing protocols?

Yes – List all out on a separate document (see [policy](https://cancer.ucsf.edu/itr/sm_files/PRMS_SC_ReviewPolicy_current.pdf) for instructions)

**Helpful Tips:**

1. *Please provide competing protocols relevant to the specific patient population(s) under evaluation.*
2. *For studies in which multiple disease-specific cohorts are being studied (e.g. “basket” protocols), please provide competing protocols for each disease type, wherever possible.*

No – **Include here a specific rationale** as to why there are no competing protocols:

Not Applicable – This is a protocol amendment review

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**Operational Feasibility Review, continued**:  Section includes information provided by CRNO

**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**:  Section includes information provided by CRNO

**Yes No N/A Comments**

Is this an investigator-initiated study?

**If Yes**, There is sufficient

financial commitment to

adequately conduct the protocol

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

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

**Additional Site Committee Input:**

**1) Molecular Imaging and Radionuclide Therapy**

***1A)*** *Does this protocol involve any* ***imaging or radiopharmaceutical agent(s)*** *with* ***therapeutic*** *intent?\**

Yes *(Please see note below for further instructions)*

No

***If Yes***, submit the protocol to the **Molecular** **Imaging & Radionuclide Therapy Site Committee** and obtain a Supplemental Site Committee Review form signed by the Chair or Co-Chair of the Molecular Imaging & Radionuclide Therapy Site Committee.

***1B)*** *Does this protocol involve any* ***experimental systemic agent(s)*** *(including chemotherapy)**combined with* ***experimental molecular imaging*** *without therapeutic intent\*?*

Yes *(Please see note below for further instructions)*

No

***If Yes***, submit the protocol to the **Molecular** **Imaging & Radionuclide Therapy Site Committee** and obtain a Supplemental Site Committee Review form signed by the Chair or Co-Chair of the Molecular Imaging & Radionuclide Therapy Site Committee.

*\* Therapeutic intent includes both protocols where the radiopharmaceutical is used to directly treat the cancer as in radioligand therapy, as well as protocols where a molecular imaging agent is used to determine a specific treatment as defined within the protocol.*

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**Additional Site Committee Input, continued:**

**2) Radiation Oncology**

***2A)*** *Does this protocol* ***involve standard of care******radiation therapy*** *combined with any form of* ***experimental systemic agent(s)*** *(including chemotherapy) with no radiation-therapy endpoints?*

Yes *(Please see note below for further instructions)*

No

***If Yes***, submit the protocol to the **Radiation Oncology Site Committee** and obtain a Supplemental Site Committee Review form signed by the Chair or Co-Chair of the Radiation Oncology Site Committee.

***2B)*** *Does this protocol involve* ***experimental******radiation therapy*** *combined with any form of* ***experimental systemic agent(s)*** *(including chemotherapy)?*

Yes *(Please see note below for further instructions)*

No

***If Yes***, submit the protocol to the **Radiation Oncology Site Committee** and obtain all relevant documents for formal Full Committee review, approval and prioritization by the Radiation Oncology Site Committee.

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

**Additional Site Committee Input, continued:**

**3) CIP/ETP**

*Was this protocol discussed with and declined by either the* ***Cancer Immunotherapeutics Program (CIP)*** *Site Committee or the* ***Experimental Therapeutics Program (ETP)*** *Site Committee?*

Yes, declined by **CIP** *(Please see note below for further instructions)*

Yes, declined by **ETP** *(Please see note below for further instructions)*

No/Not Applicable

***If Yes/Declined***, obtain proof of declination by obtaining the signature of the Chair or Co-Chair of the CIP or ETP Site Committee below ***OR*** appending email documentation from the Chair or Co-Chair of the CIP or ETP Site Committee to this form:

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

CIP or ETP Chair/Co-Chair Signature Date

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**Additional Site Committee Input, continued:**

**4) Multiple Disease Types**

*Does this protocol* ***cut across multiple disease types*** *in which you will be recruiting patients* ***from outside of this site committee****?*

Yes

No

Not Applicable – protocol will only activate at Affiliate(s) with site-limited patients

crossing multiple disease sites

***If Yes****,* you must discuss and receive verbal or written acknowledgment/approval from each relevant committee. Please indicate below which committees you have communicated with. Your signature at the end of this form is your assertion that you have communicated with the site committees checked off in the space below:

Breast Site Committee

Cutaneous Oncology Site Committee

Gastrointestinal Site Committee

Genitourinary Site Committee

Gynecologic Oncology Site Committee

Hematopoietic (Adult) Site Committee

Neurologic Site Committee

Oral, Head & Neck Site Committee

Pediatric Oncology/Pediatric Leukemia Site Committee

Supportive Care Site Committee

Thoracic Site Committee

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**Overall Scores:**

Scoring Scale: Enter numeric score (NIH scale) from 1 - 9,

One (1) being the best and nine (9) being the worst

(see attached scale on last page for guidance):

### Primary or Expedited Reviewer’s Overall Score

### Secondary Reviewer’s Overall Score       N/A

**Final Overall Score**       Note: Final Overall Score should be the **average** of the above scores

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

Concerns that Must be Addressed before Approval  None

1)

2)

3)

4)

5)

6)

7)

8)

9)

10)

Suggestions (response not required)  None

1)

2)

3)

4)

5)

6)

7)

8)

9)

10)

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

**Discussion Points Resolved During the Meeting:**  N**one**

1)

2)

3)

4)

5)

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

**Study Disposition:**

**Approval**

**Deferred for Revision**

**Disapproval**

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

Chair or Co-Chair 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 | | |