

**UCSF Helen Diller Family Comprehensive Cancer Center
Protocol Review Committee New Submission Application Form**
Form to be reviewed by the Program Site Committee prior to submitting to
the Protocol Review Committee

To Be Completed by Applicant Prior to Program Site Committee Review

Protocol Title:	
IND Number: <input type="checkbox"/> Pending <input type="checkbox"/> Assigned (provide number): <input type="checkbox"/> Not Applicable (provide reason):	
Principal Investigator:	Co-Principal Investigator:
Participating Investigators: (Those who participate in the conduct of the study)	
Is PI the author of the protocol? <input type="checkbox"/> Yes <input type="checkbox"/> No	
If No, did PI have significant input into study design or development? <input type="checkbox"/> Yes <input type="checkbox"/> No	
Does the PI have any significant financial interests related to the work to be conducted as part of the above-referenced project? <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, please specify:	
UCSF Biostatistician involved in the development/design of the trial (enter N/A if not applicable):	
Study Coordinator:	Telephone:
Primary Disease Site:	
Funding Source (check all applicable):	
Industry <input type="checkbox"/> NCI Cooperative Group <input type="checkbox"/> Department of Defense <input type="checkbox"/> Other NIH <input type="checkbox"/>	
Research/Advocacy Foundation (name) _____ <input type="checkbox"/>	
PI Discretionary Funds <input type="checkbox"/> Other (name) _____ <input type="checkbox"/> None <input type="checkbox"/>	
Will you be using any of the following? <input type="checkbox"/> CTSI CCRC (give location): <input type="checkbox"/> CTSI PCRC <input type="checkbox"/> ITI Early Phase Clinical Trials Unit	
Site(s) to Open Protocol: <input type="checkbox"/> Parnassus <input type="checkbox"/> Mount Zion <input type="checkbox"/> SFGH <input type="checkbox"/> VAMC <input type="checkbox"/> Other UCSF Sites (give locations): <input type="checkbox"/> Multicenter Sites:	
If a cooperative group trial, will you use the CIRB? <input type="checkbox"/> Yes <input type="checkbox"/> No	
Principal Investigator Signature: _____ Date: _____	

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1. Protocol Description

Phase: Pilot/Feasibility Phase I Phase I/II Disease-Specific
 Phase I/II Non-Disease-Specific Phase II Phase III
 Phase IV N/A

UCSF Involvement:

Investigator-Initiated/Single Center Investigator-Initiated/Multicenter
 Cooperative Group Industry/Single Center
 Industry/Multicenter/UCSF Input on Design/Reporting Other
 Industry/Multicenter/No UCSF Input on Design/Reporting
 Consortium (non-NCI)

If Multicenter and/or Consortium, is UCSF the Coordinating Site? Yes No

2. Accrual Information

UCSF Accrual Sites	UCSF Total Target Accrual Goal*	UCSF Annual Target Accrual Goal
MZ/Parnassus		
SFGH		
SFVAMC		
Other (name):		
Total		

*If multi-center, list the Total Target Accrual Goal for all institutions combined followed by the UCSF target accrual in parentheses, e.g., 900 (20):

Accrual Goal Justification (e.g., tumor registry data or prior accrual for similar population):

3. Prioritization

- Are there competing trials? Yes No
 - **If yes, list the prioritization order for this and all trials that are **open** or **in development** for this **patient population** or disease type (state). Identify this trial submission with an asterisk (*):
 - Please describe how competing trials will be prioritized:
 - **List **all** trials **in development** (not yet activated) for the entire site committee and identify this trial submission with an asterisk (*):
- ** Can be attached separately or listed here. Please uploaded in the Velos Version Tab.

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4. Site Committee Review

Review Forms Attached
(Primary, Secondary, Biostatistical, and Site Committee Chair Review Forms)

Date submitted to PRC

Site Committee Chair/Co-Chair Signature

Date

Site Committee Chair/Co-Chair Printed Name