

## UCSF Helen Diller Family Comprehensive Cancer Center Expanded Access Site Committee Chair/Co-Chair Approval

### EXPANDED ACCESS INFORMATION (PROVIDER TO COMPLETE)

Requesting Provider:		
Type:	Single-patient Emergency:      Yes      No	Multi-patient # of patients: _____
Investigational Product/Treatment:		
Patient Information:	Age(s): _____	
	Diagnosis/Diagnoses: _____	
Initiator of Request:	PI	Sponsor
Rationale for Request: (attach additional page if needed)		

### FOR CLINICAL RESEARCH SUPPORT OFFICE (CRSO) PROGRAMS ONLY (PROVIDER TO COMPLETE)

I agree to pay the Clinical Research Support Office (CRSO) a \$1500 fee (\$3000 if the request initiator is "Sponsor") to complete the IRB and FDA submissions and maintain regulatory compliance for the duration of the expanded access treatment. I agree to abide by the HDFCCC Single- and Multi- Patient Expanded Access Treatment Policy.

Provide COA for journal transfer: \_\_\_\_\_

Requesting Provider Signature: \_\_\_\_\_ Date: \_\_\_\_\_

CRSO Director/Designee Signature: \_\_\_\_\_ Date: \_\_\_\_\_

### BY SIGNING THIS FORM, I AGREE:

1. This expanded access treatment is a top priority for the program and has been moved ahead in the queue, which may involve delaying work on other studies.
2. This expanded access treatment is for a patient/patient population that cannot receive this investigational treatment in a clinical trial, and it is not feasible to open a clinical trial for this patient/patient population.
3. The Site Committee will assign the required resources to ensure regulatory and operations management and compliance, including clinical research coordinator effort for AE/SAE collection.
4. Record of the expanded access treatment will be registered, maintained, and closed out in OnCore.
5. The proposed expanded access program is not intended for presentation/publication and does not contain any scientific aims, statistics, or sample size calculations.

\_\_\_\_\_  
Site Committee Chair/Co-Chair Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Site Committee Chair/Co-Chair Printed Name

\_\_\_\_\_  
Select a Site Committee

\_\_\_\_\_  
Site Committee of Record