Office of Ethics and Compliance (OEC) Regulatory Support Program

FDA Audit Roles and Responsibilities

	OEC Regulatory Support	Study Team/PI	Legal/ UCSF	Legal/ BCH-O	HRPP/QIU
Audit Preparation	x				
Attend opening meeting	x				
Support study team by phone/email	x				
Attend closing meeting	x				
Provide template for 483 response	x				
Provide a draft response to Regulatory Support within 5 days		x			
Provide feedback on draft 483 response regarding FDA regulatory requirements	x				
Provide feedback on draft 483 response regarding HRPP/IRB matters					x
Provide feedback on final 483 response draft			x	x	
Revise 483 response to incorporate feedback		x			
Submit 483 response to FDA		x			

*The Helen Diller Family Comprehensive Cancer Center (HDFCCC)'s Data and Safety Monitoring Committee Director manages and supports the FDA audit process for HDFCCC studies.