ClinicalTrials.gov Registration and Reporting Roles and Responsibilities

Office of Ethics and Compliance (OEC)
Principal Investigator (PI)
Human Research Protections Program (HRPP)
Quality Improvement Unity (QIU)
ClinicalTrials.gov Protocol Registration and Reporting System (PRS)

	OEC Regulatory Support	Study Team/PI	HRPP/ QIU
Create user accounts for PIs	**X**		
Initial determination to register a study		**X**	
Final authority in deciding whether a protocol must be registered			**X**
Create study record[1]		**X**	
Pre-review study records before released to PRS	**X**		
Help study teams address review comments[2]	**X**		
Send reminders at appropriate intervals to study teams to update record and resolve errors	**X**		
Enter study results[3]		**X**	
Assist with results reporting issues[4]	**X**		

[1-4] The Helen Diller Family Comprehensive Cancer Center (HDFCCC)'s Data Integrity and Compliance team supports HDFCCC studies registered on ClinicalTrials.gov