Food and Drug Administration (FDA) Regulations Roles and Responsibilities

Office of Ethics and Compliance (OEC)
Principal Investigator (PI)
Benioff Children's Hospital – Oakland (BCH-O)
Human Research Protections Program (HRPP)
Quality Improvement Unity (QIU)
Institutional Review Board (IRB)
Investigational Device Exemption (IDE)
Investigational New Drug (IND)

	OEC Regulatory Support	Study Team/PI	HRPP/ QIU
Provide consultations on the applicability of FDA regulations	**X**		
Determine if IRB review is required			**X**
Determine drug/device requirements (i.e., exemptions, non-significant risk determinations, IDE)			**X**
Provide approved/cleared device indication/labeling documentation as part of IRB application		**X**	
Facilitate contact with FDA as needed	**X**		
Complete IND/IDE, Q-submission applications[1]		**X**	
Review IND/IDE, Q-submission applications for completeness	**X**		
Help physician navigate expanded access process	**X**		
Facilitate IRB review or IRB Chair concurrence for expanded access request			**X**

[1] HDFCCC's Clinical Research Support Office (CRSO) Regulatory Affairs supports HDFCCC studies with protocol development and editing, consent form development, full regulatory compliance, and IND/IDE filing and maintenance.