## Food and Drug Administration (FDA) Audit 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)

| | OEC Regulatory Support[1] | Study Team/PI | Legal/ UCSF | Legal/ BCH-O | HRPP /QIU |
|---|---|---|---|---|---|
| Audit Preparation | **X** | **X** | | | |
| Attend opening meeting | **X** | **X** | | | **X** |
| Support study team by phone/email | **X** | | | | **X** |
| Attend closing meeting | **X** | **X** | | | **X** |
| Provide template for FDA Form 483 response | **X** | | | | |
| Provide a draft FDA Form 483 response to Regulatory Support within 5 days | | **X** | | | |
| Provide feedback on draft FDA Form 483 response regarding FDA regulatory requirements | **X** | | | | |
| Provide feedback on draft 483 response regarding HRPP/IRB matters | | | | | **X** |
| Provide feedback on final FDA Form 483 response draft | | | **X** | **X** | |
| Revise draft FDA Form 483 response 483 response to incorporate feedback | | **X** | | | |
| Submit FDA Form 483 response to FDA | | **X** | | | |

[1] 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.