Investigator-Initiated Clinical Trials

KUMC faculty who serve as both the principal investigator and the sponsor of an investigational new drug (IND) or investigational device exemption (IDE) have significant additional responsibilities under FDA regulations. Because the investigator and KUMC assume greater responsibility in these studies, the PI must demonstrate that s/he has adequate resources to oversee the conduct of the trial, obtain and maintain IRB approval at all study sites, ensure the quality and security of the data, control the use of the test article, monitor and report adverse events, and fulfill the administrative duties required by the FDA.

Investigators who sponsor the IND or IDE are required to undergo a pre-initiation evaluation to confirm that resources exist to meet all the additional FDA requirements. At its discretion, the HSC may require additional study personnel, monitors or consultants as a condition of study approval, to ensure that these regulatory obligations are met. SOP 11.5 provides additional details on the duties of sponsor-investigators.