

Physician-Initiated Device Studies – FDA Resource List

CDRH Learn Videos

<http://www.fda.gov/Training/CDRHLearn/ucm162015.htm#bimo>

CDRH BIMO

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/BioresearchMonitoring/default.htm>

CDRH Device Advice - IDEs

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/default.htm>

Clinical Trials and IDE Guidance Documents

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/ucm162453.htm>

Significant Risk and Nonsignificant Risk Medical Device Studies

<http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126418.pdf>

Changes or Modifications During the Conduct of a Clinical Investigation

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm082145.htm>

Anne T. Hawthorn, J.D.
Special Investigations Branch
Division of Bioresearch Monitoring
Office of Compliance, CDRH FDA
301 796-6561
anne.hawthorn@fda.hhs.gov