FDA Website Links		
Topic/Guidance	**Description**	**Link/URL Address**
About the FDA	General and detailed information about the organization and mission of the FDA and all Centers	http://www.fda.gov/AboutFDA/CentersOffices/default.htm
Bioresearch Monitoring Program (BIMO) for Clinical Investigators	Compliance Program Guidance Manual for FDA Staff when conducting Clinical Investigator Inspections	http://www.fda.gov/ICECI/EnforcementActions/BioresearchMonitoring/ucm133562.htm
BIMO Inspection Metrics	Links to slides providing annual BIMO inspection metrics by fiscal year. The inspectional data cover all aspects of the FDA BIMO program for all Centers, as applicable (2007 - 2010)	http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ucm261409.htm
Code of Federal Regulations (CFR) Title 21	Search Tool for CFR - Title 21	http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm
Division of Scientific Investigations (DSI), Center for Drug Evaluation and Research (CDER) Metrics	Annual inspectional metrics for the BIMO programs overseen by the DSI in FDA's CDER (2003 – 2010).	http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDER/UCM256376.pdf
Guidance for Industry Investigator Responsibilities — Protecting the Rights, Safety, and Welfare of Study Subjects	An overview of the responsibilities of an investigator. Goal of this guidance is to help investigators better meet their responsibilities with respect to protecting human subjects and ensuring the integrity of the data from clinical investigations.	http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM187772.pdf
ICH E6: Good Clinical Practice: Consolidated Guidance `	International Conference on Harmonization (ICH) guidance provides a unified standard for the European Union, Japan, and the United States to facilitate the mutual acceptance of clinical data by the regulatory authorities in those jurisdictions.	http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073122.pdf

FDA Website Links		
Topic/Guidance	**Description**	**Link/URL Address**
Information Sheet Guidance For IRBs, Clinical Investigators, and Sponsors	FDA Guidance For IRBs, Clinical Investigators, and Sponsors regarding FDA Inspections of Clinical Investigators	http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126553.pdf
Inspection Observations Database	Spreadsheets summarizing the areas of regulation cited on FDA's system-generated 483s are available by fiscal year on the menu links on this page.	http://www.fda.gov/ICECI/EnforcementActions/ucm250720.htm
Inspection Classification Database	Searchable database of all final inspection classifications for inspections conducted of clinical trial investigators, Institutional Review Boards (IRB), and facilities that manufacture, process, pack, or hold an FDA-regulated product that is currently marketed.	http://www.fda.gov/ICECI/EnforcementActions/ucm222557.htm
Inspector Field Management Directives	The primary method for distributing procedural information/policy on the management of Office of Regulatory Affairs (ORA) field activities.	http://www.fda.gov/ICECI/Inspections/FieldManagementDirectives/default.htm
Investigations Operations Manual	Primary guidance document on FDA inspection policy and procedures for field investigators and inspectors	http://www.fda.gov/ICECI/Inspections/IOM/default.htm
Running Clinical Trials	Centralized information and FDA links specific to running clinical trials; includes links to BIMO information, FDA Guidance documents and other resources for Clinical investigators and staff	http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/default.htm
United States Food and Drug Association (FDA) Web Site	Main (home) page for the US FDA web site	http://www.fda.gov/default.htm
Warning Letters	Searchable database of all FDA Warning Letters issued since 1996	http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/default.htm

Other Regulatory Links		
Topic/Guidance	**Description**	**Link/URL Address**
***Challenges to FDA's Ability to Monitor and Inspect Foreign Clinical Trials,* Department of Health and Human Services (DHHS) June 2010 Report**	June 2010 DHHS report on challenges to the FDA's ability to monitor and inspect international clinical trials.	http://oig.hhs.gov/oei/reports/oei-01-08-00510.pdf
Quality Management		
Topic/Guidance	**Description**	**Link/URL Address**
DAIDS Requirements for Clinical Quality Management Plans (CQMP)	DAIDS Clinical Research Policies and Standard Procedures - Requirements for CQMP; includes links to appendices (Sample CQMP, Chart Review Tool, Regulatory File Review Tool, Summary of Activities Tool, and CQMP Annual Summary Tool)	http://www.niaid.nih.gov/LabsAndResources/resources/DAIDSClinRsrch/Pages/ClinicalSite.aspx