A partial list of resources for use in developing a protocol or designing or implementing a trial.

* [21 CFR Part 11: Electronic Records, Electronic Signatures](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=11)
* [21 CFR Part 50: Protection of Human Subjects](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=50)
* [21 CFR Part 56: Investigational Review Boards](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=56)
* [21 CFR Part 312: Investigational New Drug Application](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRsearch.cfm?CFRPart=312)
* [21 CFR Part 600: Biological Products: General](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=600)
* [21 CFR Part 812: Investigational Device Exemptions](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRsearch.cfm?CFRPart=812)
* [45 CFR Part 46; Protection of Human Subjects Research](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html)
  + International Conference on Harmonisation. 1995. E3:Structure and Content of Clinical Study Reports. Geneva, Switzerland. <http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E3/E3_Guideline.pdf>
  + International Conference on Harmonisation (2015). E6(R2): Guideline for Good Clinical Practice. Geneva, Switzerland: <http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R2__Addendum_Step2.pdf>
  + International Conference on Harmonisation (2014). Final Concept Paper E9(R1): Addendum to Statistical Principles for Clinical Trials. Geneva, Switzerland: <http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/%20Efficacy/E9/E9__R1__Final_Concept_Paper_October_23_2014.pdf>.
  + International Conference on Harmonisation (2016). E17: General Principles for Planning and Design of Multi-Regional Clinical Trials Guidance for Industry. Geneva, Switzerland: <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM519603.pdf>
  + Food and Drug Administration (2006) Guidance for Clinical Trial Sponsors: Establishment and Operation of Clinical Trial Data Monitoring Committee <http://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm127073.pdf>
  + Food and Drug Administration Center for Drug Evaluation and Research (2009). (DRAFT) Guidance for Industry: Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims. Silver Spring, Maryland: <http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm193282.pdf>
  + Food and Drug Administration Center for Drug Evaluation and Research (2010). (DRAFT) Guidance for Industry: Adaptive Design Clinical Trials for Drugs and Biologics. Silver Spring, Maryland: <http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm201790.pdf>
  + Food and Drug Administration Center for Drug Evaluation and Research (2016). Guidance for Industry: Non-Inferiority Clinical Trials. Silver Spring, Maryland: <http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm202140.pdf>
  + FDA Guidance for Industry, Providing Regulatory Submissions in Electronic Format - Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications. <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM333969.pdf>
  + FDA Guidance for Industry, Providing Regulatory Submissions in Electronic Format — Standardized Study Data. <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM292334.pdf>
  + FDA Draft Guidance for Industry: Enrichment Strategies for Clinical Trials to Support Approval of Human Drugs and Biologic Products. <https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm332181.pdf>
  + Principles for Codevelopment of an In Vitro Companion Diagnostic Device with a Therapeutic Product

<https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm510824.pdf>

* + FDA Draft Guidance for Industry: Pregnancy, Lactation and Reproductive Potential: Labeling for Human Prescription Drug and Biological Products – Content and Format(Dec2014).

<https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM425398.pdf>

* + FDA Guidance for Industry: Clinical Trial Endpoints for the Approval of Cancer Drugs and Biologics.

<http://www.fda.gov/downloads/Drugs/Guidances/ucm071590.pdf>

* + FDA Guidance for Industry and Investigators Safety Reporting Requirements for INDs and BA/BE Studies

<http://www.fda.gov/downloads/Drugs/Guidances/UCM227351.pdf>

* + FDA Draft Guidance to Industry: Multiple Endpoints in Clinical Trials <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM536750.pdf> January 2017.
  + FDA Guidance for Industry, M3(R2) Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals

<https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm073246.pdf>

* Informed Consent Information Sheet Guidance for IRBs, Clinical Investigators, and Sponsors <http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM405006.pdf>,

NOTE: Lists of References may be found within the specific Therapeutic Area libraries, and these may also be useful resources for protocol authors.