Selected List of Resources for IDE

Before Trial

Pre-IDE (Consultation)

FDA Guidance

- Q-Submission Program: Requests for Feedback and Meetings (Medical Device)
- Significant Risk and Nonsignificant Risk Medical Device Studies
- IDEs for Early Feasibility medical device Clinical Studies & First in Human (FIH) Studies
- FDA Decisions for IDEs

Other Useful Links

- IDE Exempt Investigations
- In Vitro Diagnostic (IVD) Device Studies -Frequently Asked

IDE Material Preparation & Submission

IDE Submission to CDRH

- eCopy Program- FDA guidance
- eCopy Program Instructions
- eSubmitter-eCopies Tool
- eSubmitter Quick Guide
- IDE Application

Other useful links

- Combination Product Contacts
- CDRH Contact
- Sponsor Responsibilities for Significant Risk Device Studies
- Sponsor Responsibilities for Nonsignificant Risk Device Studies
- Investigator Responsibilities for Significant Risk Device Studies
- Investigator Responsibilities for

During Trial

Maintenance Activities

Amendments

- FDA Guidance: Changes or Modifications During the Conduct of a Clinical Investigation
- IDE Modifications

IDE Reports

- Sponsor Reports
- Suggested Format for IDE Progress Report
- Suggested Format for IDE Final Report
- Investigator Reports
- Investigator Annual Progress Reports

Other useful links:

- Human Subject Protection; Acceptance of Data From Clinical Investigations for Medical Devices

End of Trial

Withdraw/Termination

- Suggested Format for IDE Final Report
- Investigator Final Reports