## **FDA**

## Requirements

Clinical Investigator (individual who conducts the study)

**FDA** 

- FDA 1572 (drug)
- Investigator Agreement (device)
- Serious Adverse Event reports submitted to Sponsor

Sponsor-Investigator (individual who initiates and conducts the study)

- Clinician Investigator Requirements
- Original applications and all subsequent submissions to the FDA:
  - IND Application (drug)
  - IDE Application (device)
- Amendments to the Application-IDE
- Adverse Event Reports
- Annual Reports IND and IDE
- Form 3674, Certification of Registration to ClinicalTrials.gov

## **Tips / Additional Information**

- The form <u>FDA 1572/Investigator Agreement</u> identifies the facilities where the research will take place, the
  reviewing/approving IRB and sub-investigators participating in the study. The 1572 should be updated if
  changes are made during the course of the investigation.
- An <a href="IND Application">IND Application</a> must be filed when a sponsor wishes to test a newly developed drug or the use of a drug that is not yet approved by the FDA for marketing (21 CFR 312).
- The <u>Form FDA 1571</u> is the cover sheet for the Investigational New Drug Application and should be included in all subsequent submissions to the FDA. Instructions can be found <u>here</u>.
- An IDE Application must be filed for any device that poses significant risk (21 CFR 812).

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