FDA

Requirements

Clinical Investigator (individual who conducts the study)

- 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 FDA 1572/Investigator Agreement 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 IND Application 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 Form FDA 1571 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 here.
- An IDE Application must be filed for any device that poses significant risk (21 CFR 812).

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