

[FDA](#)

[Requirements](#)

Clinical Investigator (individual who conducts the study)

- [FDA 1572 \(drug\)](#)
- [Investigator Agreement \(device\)](#)
- [Investigator Responsibilities - Safety Reporting for Investigational Drugs and Devices](#)

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).

Last updated: 28 Jan 2026

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