

FDA Fact Sheets: Investigational Device Exemption (IDE)

An investigational device exemption (IDE) allows a medical device that has not received marketing clearance or approval to be shipped for use in a clinical study without complying with other regulations of the Federal Food, Drug and Cosmetic Act. All investigational devices fall under one of the following categories:

- Significant Risk (SR);
- Nonsignificant Risk (NSR); or
- IDE Exempt

Significant risk devices are the only kind of investigational device requiring an IDE application to FDA. These devices must comply with the full IDE regulations (21 CFR 812). SR devices are defined as presenting a potential for serious risk to the health, safety, or welfare of a subject and include devices used as implants; devices intended to support or sustain human life; and devices used for diagnosing, curing, mitigating, treating or otherwise preventing impairment of human health.

Nonsignificant risk devices by definition do not pose significant health risk to patients and do not require an IDE application to FDA. They are subject to abbreviated IDE regulations and must be approved by an institutional review board (IRB).

Investigations involving many diagnostic devices, as well as legally marketed devices being used in accordance with their cleared/approved intended use, are exempt from IDE regulations.

Before the submission of an IDE application, sponsors may request to meet with FDA as part of the pre-submission process to solicit the agency's feedback on a variety of clinical issues.

An IDE application submitted to FDA must include: a report on prior investigations, an investigational plan, a description of the device's manufacturing, certification of investigator approval, information on the reviewing IRB, locations of investigation sites, amount charged for the device, copies of labeling, and copies of informed consent forms. While FDA may withhold approval pending receipt of needed information, failure to request information within 30 days of receipt results in the IDE being "deemed approved."

Once a device has IDE approval (from an IRB or an IRB and FDA) a clinical investigation can begin. All clinical investigations require that investigational devices must be labeled properly and the study must be conducted in accordance with Good Clinical Practices (GCP). GCP is the term for the regulations and requirements that must be adhered to

during a clinical study and includes regulation and requirements on IDEs, protection of human subjects (informed consent), IRBs, financial disclosure by investigators, and design controls.