**Investigational Device Studies**

A medical device is defined, in part, as any health care product that does not achieve its primary intended purposes by chemical action or by being metabolized.

An investigational device is a medical device that is the object of a clinical study designed to evaluate the effectiveness and/or the safety of the device. All investigational device use must have prior IRB review and approval by the IRB in accordance with applicable laws and regulations [FDA 21 CFR 812 and 814 Subpart H].

Clinical investigations of medical devices will comply with regulation [21 CFR 812](https://www.fda.gov/regulatory-information/search-federal-regulations) unless otherwise exempt, as noted below.

**Significant Risk (SR) and Non-Significant Risk (NSR)**

There are two possible classifications for investigational medical devices:

- Significant Risk (SR) or
- Non-Significant Risk (NSR)

Unless exempt from Investigational Device Exemption (IDE) regulations, an investigational device must be categorized as either a Significant Risk (SR) device or a Non-Significant Risk (NSR) device.

The initial risk assessment is determined by the sponsor, but the IRB must review the sponsor’s SR or NSR determination and will modify the determination if the full board disagrees with the sponsor. When the FDA makes the SR or NSR determination for a study, its determination is final.

**Significant Risk (SR)**

SR device studies must be conducted in accordance with the full IDE requirements [21 CFR part 812], and may not commence until 30 days following the sponsor's submission of an IDE application to FDA. The study may not commence until FDA has approved the IDE application and the IRB has approved the study.

A SR device study is defined as a study of a device that presents a potential for serious risk to the health, safety, or welfare of a subject and 1) is intended as an implant, or 2) is used in supporting or sustaining human life, or 3) is of substantial importance in diagnosing, curing, mitigating or treating a disease, or otherwise prevents impairment of human health, or 4) otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.

**Non-Significant Risk Device (NSR)**

A NSR device study is one that does not meet the definition of a SR study. NSR are not necessarily minimal risk studies.

NSR device studies do not require submission to the FDA. These studies must comply with the abbreviated regulations set forth in [21 CFR 812.2(b)](https://www.fda.gov/regulatory-information/search-federal-regulations) that require a device fulfill the following requirements:
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- The device is not a banned device
- The sponsor labels the device in accordance with 21 CFR 812.5
- The sponsor obtains IRB approval of the investigation after presenting the reviewing IRB with a brief explanation of why the device is not a significant risk device, and maintains such approval.
- The sponsor ensures that each investigator participating in an investigation of the device obtains from each subject under the investigator's care, consent und 21 CFR 50 and documents it, unless documentation is waived.
- The sponsor complies with the requirements of 21 CFR 812.46 with respect to monitoring investigations;
- The sponsor maintains the records required under 21 CFR 812.140(b) (4) and (5) and makes the reports required under 21 CFR 812.15(b)(1) through (3) and (5) through (10);
- The sponsor ensures that participating investigators maintain the records required by 21 CFR 812.140(a)(3)(i) and makes the reports required under 812.150(a) (1), (2), (5) and (7); and
- The sponsor complies with the prohibitions in 21 CFR812.7 against promotion and other practices.

Please see the FDA Information Sheets for examples of SR and NSR devices:
http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/ucm113709.htm

Investigational Device Exemption (IDE)

An investigational device exemption (IDE) allows the investigational device to be used in a clinical study in order to collect safety and effectiveness data required to support requests to legally market the device. Investigational use also includes clinical evaluation of certain modifications or new intended uses of legally marketed devices. All clinical evaluations of investigational devices, unless exempt, must have an approved IDE before the study is initiated.

In general, requirements for clinical evaluation of devices that have not been cleared for marketing include the following:

- If the study involves a significant risk device (see below), the IDE must be approved by the FDA and the IRB, and
- Informed consent must be obtained from all subjects, and
- Labeling must indicate that the device is for investigational use only, and
- Provisions must be made for monitoring of the study, and
- Required records and reports must be submitted, as applicable (e.g., to the IRB, the sponsor or the FDA).