

Section 13: Medical Devices

A medical device is defined as an instrument, apparatus, implement, machine, contrivance, implant, *in vitro* reagent, or other similar or related article, including a component part or accessory which is:

1. Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
2. Intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.

Medical devices include, but are not limited to pacemakers, dialysis equipment, breast implants, bandages, thermometers, glucose pumps, wheelchairs, scalpels and contact lenses.

Devices, both investigational and FDA-approved, are regulated by the Center for Devices and Radiological Health (CDRH), a division within the FDA. The specific regulations that apply to devices are:

- [21 CFR Part 812 - Investigational Device Exemptions](#)
- [21 CFR Part 58 - Good Laboratory Practice for Non-clinical Laboratory Studies](#)
- [21 CFR Part 820 - Quality System Regulation](#)

The Investigational Device Exemption (IDE) is comparable to the Investigational New Drug application (IND). The IDE allows a sponsor to use an investigational device in a clinical study in order to collect safety and effectiveness data required to support a Pre-market Approval (PMA) application or a Pre-market Notification [510(k)] submission. The PMA is similar to the New Drug Application (NDA) used for drugs and biologics. The 510(k) is used to prove substantial equivalence to an FDA approved device.

There are two types of device studies:

1. **Significant risk (SR):** A SR device study is defined by the regulations (21 CFR 812.3) as one that presents a potential for serious risk to a participant. In order to conduct a SR study, the sponsor must submit an IDE to the FDA as well as obtain IRB approval prior to study initiation
2. **Non-significant risk (NSR):** A NSR study, on the other hand, does not. In order to conduct an NSR study, an investigator must first submit a proposal to the IRB. If the IRB concurs with the investigators/sponsor's NSR determination, the study may be initiated upon their final approval

The procedures for ordering, storage, handling, shipping, recording and destroying investigational devices are consistent with the guidelines and regulations of the FDA and all other applicable rules and laws.

13.1 Definition

A "device" is any device used for clinical research that is supplied by the sponsor of the trial for use in an IRB approved protocol.

13.2 Ordering

The Principal Investigator identified on the IRB approved protocol will be the physician under which the investigational device will be ordered. The device will be ordered as per the sponsor's instructions. The order will supply all information required to accurately fill the order and permit proper recording.

13.3 Storage

All investigational devices will be stored under control of the Principal Investigator. This may be in the PI's office or in a specialized laboratory such as the Cell Manipulation Laboratory.

13.4 Authorization

The physician will obtain formal written patient consent and authorization prior to using any investigational device. This consent process and document must have documented IRB approval.

13.5 Dispensing

The Principal Investigator, or designated specialized laboratory, will be responsible for dispensing the investigational device per protocol and department policies and procedures. Each protocol has its own device supply. The transfer of devices between protocols is prohibited. If this is required, the sponsor of the trial must be notified and approval granted. For NCI-sponsored device trials, if under extenuating circumstances devices are transferred between studies, a device transfer form must be completed. All pertinent device accountability records will be maintained by the PI or designated specialized laboratory.

13.6 Destroying

Used investigational devices will be destroyed according to the department's waste handling procedures. Any unused/unopened investigational devices will be returned to the trial sponsor for destruction, unless authorized by the trial sponsor to destroy on site.