**What is an Investigational Device?**

An investigational device is a medical device which is the subject of a clinical study designed to evaluate the effectiveness and/or safety of the device. A device is considered investigational if either condition applies:

* The device is not approved for marketing in the U.S. *or*
* The device is approved for marketing but is being *clinically* evaluated for a new indication.

The [Food and Drug Administration (FDA)](http://www.fda.gov/MedicalDevices/) regulates research involving medical devices ([see FDA definition](http://www.fda.gov/AboutFDA/Transparency/Basics/ucm211822.htm)), as well as all aspects of device manufacturing, marketing, and distribution (*Code of Federal Regulations* Title 21, parts 800-1299). The FDA website contains several sets of useful and readable guidance documents about investigational devices, including [general wellness](https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm429674.pdf) devices and [mobile medical applications](https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366.pdf).

**IRB Submission and Reporting Requirements**

If your study involves a device, you must provide information about the device in the IRB Application and consent form, and submit any applicable supporting documents\*.

For those studies involving use of an **investigational device**, the investigator (or sponsor) must obtain either:

1. “Significant risk" [Investigational Device Exemption (IDE)](https://irb.ucsf.edu/node/721) from the FDA, *or*
2. A determination of "non-significant risk" from the IRB, *or*
3. Verification that the device is “exempt” from IDE requirements by the IRB.

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| **Type:** | **Requirements:** | **Examples:** |
| **Significant Risk (SR) Device** | [21 CFR 812.3](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=812) defines a SR device as an investigational device that: | ▪ Non-invasive, EEG Devices. ▪ Artificial skin and interactive wound and  burn dressings,▪ Intravascular stents▪ Cardiac pacemakers▪ Rebreathing Devices▪ Synthetic Polymer Materials▪ Infusion Pumps▪ Contraceptive Devices |
| Is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject; |
| Is purported or represented to be for a use in supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject; |
| Is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject; or |
| Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject. |
| **Non-significant risk (NSR) Device** | A NSR device is one that does not meet the definition of a SR device. See [21 CFR 812.2](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.2) regarding applicability. | ▪ EEG use for determining brain  activity. ▪ Daily wear contact lenses  |
| **“Exempt” Device** | A device that is exempt from the IDE requirement under [21 CFR 812](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.2). Investigators must submit information to the IRB that evidences such. | ▪ An approved device used in research  according to its approved labeling.▪ Device consumer preference testing.▪ Particular in vitro diagnostic studies. |

\*Additional supporting information should be submitted, as appropriate. The IRB should also be informed if the FDA or any other IRB has determined the device to present SR or NSR, and provide any further information requested by the IRB.

The FDA's ["Significant Risk and Nonsignificant Risk Medical Device Studies" Information Sheet](http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126418.pdf) provides criteria for assistance in making these determinations.

**IRB Determination of Significant vs. Non-significant Risk**

Investigators may not make their own device determinations. The IRB will determine the device’s ***risk status*** using information such as:

* The nature of the harm that may result from the use of the device (e.g., potentially life-threatening, could result in impairment or permanent damage, etc.).
* The study procedures (e.g., includes surgical procedures) and if the investigation itself is approvable.
* The investigator/sponsor’s risk designation and justification criteria.
* Reports regarding prior investigations of the device.

The IRB may agree or disagree with the investigator's or sponsor's initial device risk assessment.

1. If the IRB agrees to a NSR determination, the investigation may proceed without FDA approval after the IRB approves the study.
2. If the IRB determines the device to be a significant risk (SR), the study can only be conducted at this institution as a study involving a SR device, and the investigator or sponsor must notify the FDA that a SR determination has been made for the device.

While the IRB is serving as FDA's surrogate with respect to review and approval of NSR devices, **The FDA has the ultimate decision in determining if a device is SR or NSR**. On some occasions, FDA may overrule the IRB's decision that a device presents NSR or SR.

1. When FDA overrules an IRB's NSR determination, an IDE application must be submitted to FDA.
2. When FDA considers the device to be NSR, FDA may return an IDE application to the investigator or sponsor. The IRB must then determine if it wants the study to take place at this institution as a NSR device investigation.