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## Significant vs. Non-Significant Risk Devices

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### Definitions

FDA regulations state that for studies involving use of an investigational device, the investigator (or sponsor) must obtain either a "significant risk" Investigational Device Exemption (IDE) <sup>[1]</sup> from the FDA, or a determination of "non-significant risk" from the IRB.

The FDA's "Significant Risk and Nonsignificant Risk Medical Device Studies" Information Sheet <sup>[2]</sup> provides criteria for the investigator and IRB to use in making these decisions. Also see the **UCSF Investigator Checklist for IDE Exempt, Non-Significant, and Significant Risk Device Studies** <sup>[3]</sup> for a quick overview of when an IDE from the FDA is required or not required.

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21 CFR 812.3 <sup>[4]</sup> defines a SR device as an investigational device that:

**Significant risk (SR) device**

1. Is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject;
2. 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;
3. 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
4. Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.

Examples: Artificial skin and interactive wound and burn dressings, intravascular stents, bronchial tubes. See the FDA info sheet <sup>[2]</sup> for more examples.

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**Non-significant risk (NSR) device**

A NSR device is one that does not meet the definition of a SR device.

Examples: Low-power lasers for treatment of pain and daily-wear contact lenses. See the FDA info sheet <sup>[2]</sup> for more examples.

## **IRB Application Requirements**

If the investigator or sponsor believes a device poses non-significant risk, complete the "Non-Significant Risk Determination for an Investigational Device" section in the IRB Application.

Additional supporting information should be submitted, as appropriate ? see the IRB submission info on the Investigational Devices page <sup>[1]</sup> for more details. 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.

## **Making the Significant vs. Non-significant Risk Determination**

The IRB must make two separate decisions, based on different criteria.

1. Is the investigation approvable or not? ? The criteria for deciding if a study involving either a SR or NSR device can be approved are the same as those used to evaluate any proposed research project.

2. Does the device present SR or NSR? ? The IRB review criteria and review process are described below.

## **IRB's Criteria for Determining SR vs. NSR**

What is the basis for the risk determination?

The determination of significant risk depends on the use of the device in the particular study, as well as the inherent risks of the device itself.

What is nature of harm that may result from the use of the device?

SR studies are those that present a potential for serious risk to the health, safety, or welfare of a subject. Included among those devices that present SR are devices for which the potential harm to subjects could be life-threatening, could result in permanent impairment of a body function, or permanent damage to body structure, or could necessitate medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to body structure.

Will the subject need to undergo an additional procedure as part of the investigational study?

If the subject must undergo a procedure as part of the study, e.g., a surgical procedure to implant the device, the IRB must consider the potential harm caused by the procedure, as well as the potential harm caused by the device.

Examples:

- A pacemaker that is a modification of a commercially available pacemaker poses SR because the use of any pacemaker presents a potential for serious harm to the subjects. This is true even though the modified pacemaker may pose less risk, or only slightly greater risk, in comparison to the commercially available model. The degree of possibly reduced or increased risk associated with the investigational pacemaker should only be considered (in relation to possible decreased or increased benefits) when assessing the approvability of the study.
- An extended-wear contact lens is considered SR because wearing the lens continuously for 30 days presents a potential for injuries not normally seen with daily wear lenses, which are considered NSR.

## **SR vs. NSR Determination**

The IRB may agree or disagree with the investigator's or sponsor's initial NSR assessment. If the IRB agrees with the NSR determination, the investigation may proceed without FDA approval after the IRB approves the study.

If the IRB disagrees with the NSR determination

The study can only be conducted at this institution as a study involving a SR device. The investigator or sponsor must notify the FDA [5] that a SR determination has been made for the device (whether or not the study is ultimately conducted at that institution), per 21 CFR 812.150(9) [5]. The study can be conducted as an SR investigation following FDA approval of an IDE application [1].

FDA may overrule

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. When FDA overrules an IRB's NSR determination, an IDE application must be submitted to FDA.

On the other hand, 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.

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**Links**

[1] <https://irb.ucsf.edu/investigational-devices>

[2] <http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126418.pdf>

[3] <https://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/device-checklist.pdf>

[4] <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=812>

[5] <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.150>