### Significant Risk (SR)
- SR devices require full committee review upon initial review and at continuing review (at least annually).
- Use of an SR device requires an Investigational Device Exemption (IDE) and must follow all of the IDE regulations at 21 CFR 812.
- The FDA is the final arbiter of whether device is SR. The Researcher may include documentation from the FDA of the risk assessment. When this occurs, the IRB does not need to make a formal determination.
- The IRB must document the SR assessment in the meeting minutes upon initial review.
- SR assessment based solely on seriousness of harm that may result from the use of the device in an investigation, not on the device alone.
- Reassessment of SR may occur based on modifications that involve a risk or other changes that may affect risk determination.
- IRB further considers if study should be approved or not as per criteria for IRB approval and applicable UC/UCI policies.
- Evidence of IDE needed before IRB approval may be granted (e.g. FDA determination letter, IDE # listed on Sponsor Master Protocol).

**SR Examples:**
- Surgical lasers for use in medical specialties
- Tissue adhesives for neurosurgery, gastroenterology, ophthalmology, general & plastic surgery and cardiology
- Cardiac bypass & assist devices

### Nonsignificant Risk (NSR)
- NSR devices require full committee review upon initial review. The IRB must document the NSR assessment in the meeting minutes upon initial review.
- Use of an NSR device DOES NOT require an Investigational Device Exemption (IDE).
- The FDA is the final arbiter of whether device is NSR. The Researcher may include documentation from the FDA of the risk assessment. When this occurs, the IRB does not need to make a formal determination.
- NSR assessment based solely on seriousness of harm that may result from the use of the device in an investigation, not on the device alone.
- Reassessment of NSR may occur based on modifications that involve a risk or other changes that may affect risk determination.
- If determined NSR, future reviews may be expedited via category 9 if criteria is met. This should be documented in the minutes at time of review. **May be category 1b if sponsor provided a FDA NSR determination letter at initial submission.**
- IRB further considers if study should be approved or not as per criteria for IRB approval and applicable UC/UCI policies.
- Researchers that use NSR devices as part of their IRB approved research study must follow ABBREVIATED requirements per 21 CFR 812.2(b).

**NSR Examples:**
- Low power laser for pain treatment
- Externally worn monitor for insulin RXN
- Dental filling material made from traditional materials
- Daily wear contact lenses

### Exempt
- May qualify for expedited review, category # 1b.
- Exempt = exempt from IDE requirements (21 CFR 812) - with some exceptions.
- 7 exemption categories in 21 CFR 812.2 (C)
- The first two categories for exemption pertain to devices that were either manufactured before 1976 or similar products manufactured after 1976 (referred to as a 510K device).
- A 510K device is manufactured after 1976 and is determined as substantially equivalent to a device in commercial distribution.
- Includes diagnostic device studies (e.g. in vitro diagnostic studies) as long as sponsor complies with 21 CFR 809.10 (C).
- Categories 3 (diagnostic device that meets specific criteria) and 4 (consumer preference testing, testing of a modification or combination) are the most commonly applied for exemptions.
- An exempt study being conducted to collect data to support either a clinical investigation or marketing application must comply with 21 CFR 50 (protection of human subjects) and should comply with 21 CFR 56 (IRB).

**Exempt Examples:**
- Consumer preference testing
- Testing of a device modification
- Testing of 2 or more devices in commercial distribution if the testing does not collect safety and efficacy data or put subjects at risk